TO COMPARE THE EFFECT OF INDUCING AGENTS DINOPROSTONE SUSTAINED RELEASE VAGINAL PESSARY AND INTRACERVICAL GEL ON LABOUR AND ITS FETOMATERNAL OUTCOME

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DECLARATION

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Dedicated

To

My

Parents

And

Teachers

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ABSTRACT

Introduction: The use of dinoprostone is an effective method for cervical ripening and IOL. It is available as a gel, pessary or tablet form. The pessary form has recently been introduced as a method for IOL with an advantage of 24 hour sustained release. There are limited number of studies to show the comparison of different preparations of dinoprostone on IOL.

Aim of study: A prospective randomized study to compare the effect of inducing agents dinoprostone sustained release vaginal pessary and intracervical gel on labour and its fetomaternal outcome.

Materials and Methods: Patients were randomly distributed into two groups according to the dinoprostone preparation used, Group A (intravaginal pessary) and Group B (intracervical gel). Patients with successful induction in group A formed group C; and in group B formed group D respectively. The data on the safety and efficacy of both agents were analyzed using t-test and chi-square test of all the groups.

Results: A higher rate of successful induction was seen in primigravidas who were induced with pessary as compared to multigravidas who responded better with gel preparation. The number of per vaginal examinations were significantly higher in those receiving the gel preparation. A higher level of patient satisfaction was noted in patients receiving the pessary. There was no statistical significance in the number of maternal and fetal adverse events in both the groups.

Conclusion: Both preparations of dinoprostone; gel and pessary were equally safe and efficacious for IOL.

Keywords: prostaglandin E2, dinoprostone, IOL: induction of labour.

ABBREVATIONS

ACOG	American College Of Obstetrics And Gynecologists
FDA	Food And Drug Administration
FHR	Fetal Heart Rate
FIGO	International Federation Of Gynecology And Obstetrics
IOL	Induction Of Labour
MBS	Modified Bishop's Score
MSL	Meconium Stained Liquor
NICE	National Institute For Health And Care Excellence
NICU	Neonatal Intensive Care Unit
PG	Prostaglandin
PGE1	Prostaglandin E1
PGE2	Prostaglandin E2
PGF2	Prostaglandin F2
PPH	postpartum hemorrhage
PV	Per vaginum
RCOG	Royal College Of Obstetricians And Gynaecologists
RCT	Randomized Controlled Trials
UN	United Nations
US	United States
WHO	World Health Organization

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INTRODUCTION

Induction of labour is one of the most commonly performed procedures in obstetrics. In developing countries, up to 25% of all pregnant women undergo induction of labour at term[1]. The rate of induction of labour has more than doubled over the past few years. It rose 2.5 fold from 9.5 % in 1991 to 23.8% in 2015[2].

There have been 211 deaths per 100,000 live births worldwide, according to UN inter-agency estimates due to pregnancy and delivery related complications[3]. Haemorrhage, hypertensive disorders, and sepsis are leading causes of maternal mortality worldwide. Thus, it is necessary to take adequate measures to decrease the maternal mortality rate, which is achieved by timely induction of labour. This prevents maternal complications from uncontrolled hypertension, diabetes, infection and shock. It also improves neonatal and perinatal outcome.

The goal of induction of labour is artificial initiation of uterine contractions before the onset of spontaneous labour that leads to progressive dilatation and effacement of cervix to achieve a vaginal delivery [4]. Induction should be carried out for various fetal and maternal conditions, where the risks of continuing the pregnancy outweigh that of delivery. These conditions include post term pregnancy, maternal hypertension, gestational diabetes, oligohydramnios, and pre labour rupture of membranes, infections, chronic maternal conditions, bleeding, fetal growth restriction and other conditions. Labour is also induced due to maternal request, although this is not supported by the recent guidelines[5].

Induction of labour is associated with certain risks like uterine hyper stimulation, non-reassuring fetal heart rate status and increased chances of operative delivery. It interferes with the natural process of child birth, with each inducing agent having its own side effects. Induction should therefore be carried out in with close fetal and maternal monitoring[6].

There are various methods for induction of labour, which include traditional, mechanical, pharmacological and surgical methods. The

traditional methods include castor oil, acupuncture, herbal remedies, breast and nipple stimulation and sexual intercourse. These methods are used in selected Indian populations. Mechanical methods include osmotic dilators like laminaria tents and balloon catheter. Surgical methods include membrane stripping and amniotomy. Pharmacological approaches to induction of labour include the use of oxytocin and prostaglandins (PGE1 and PGE2). Among the pharmacological methods, oxytocin is the most commonly used method. It can be used for both induction and augmentation of labour, however it does not have a direct effect on condition of the cervix. The use of oxytocin alone has been compared to prostaglandins. The use of prostaglandins was associated with increased chances of vaginal birth in 24 hours, and a lower caesarean section rate[7]. Hence, prostaglandins seem to be the preferred method for induction of labour.

PGE1 and PGE2 are forms of synthetic prostaglandins. They promote a number of biochemical and biophysical changes that lead to cervical ripening and an increase in myometrial contractility. The aim of these preparations is to mimic the physiological sequence of cervical effacement and dilatation followed by uterine contractions that occurs during labour[8].

A synthetic PGE1 analogue, misoprostol can be administered intra vaginally, orally, or sublingually and is used for both cervical ripening and induction of labour. However it has not yet been approved for use for induction of labour, except for its use for induction in intrauterine fetal demise by the Drugs Controller General of India[9].

PGE2 (dinoprostone) is available as a gel, pessary or tablet form. It is available as a controlled release 0.3 mg/hr; 10 gm reservoir intravaginal pessary, as an intracervical gel containing 0.5 mg gel in a single use syringe and intravaginal tablets containing 3 mg dinoprostone. PGE2 is the preferred method of induction of labor as unless there are specific contraindications to its use[10]. As compared to oxytocin or placebo alone, the use of prostaglandins for cervical ripening increase the likelihood of

delivery within 24 hours[11]. However, these formulations are known to cause uterine tachysystole. Maternal side effects such as fever, diarrhoea, vomiting, although these are less common.

The slow release PGE2 vaginal pessary, has various advantages over its gel form such as easy administration, less number of vaginal examinations, it allows for easy removal if tachysystole develops[12]. The intracervical gel administration can be uncomfortable and inconvenient; moreover its accurate administration requires skill. The spillage of gel from cervical canal into the vagina can result in reduced efficacy. The studies showing the benefit of dinoprostone gel and pessary are limited.

We have compared dinoprostone gel and pessary for use in cervical ripening and studied their effectiveness for induction of labour and their impact on fetomaternal outcome.

AIMS AND OBJECTIVES OF THE STUDY

To compare the effect of inducing agents dinoprostone sustained release vaginal pessary with intracervical gel on labour and its fetomaternal outcome.

REVIEW OF LITERATURE

Induction of labour is stimulation of uterine contractions before the onset of spontaneous labour, with or without ruptured membranes [13]. When cervix is close and uneffaced, labour induction begins by opening up and softening of the cervix.

Induction of labour is indicated when the benefits of termination of pregnancy outweigh its risks[14]. Labour can be induced for various maternal and fetal conditions, after taking into account the cervical status and gestational age, and the severity of maternal and fetal condition. Induction of labor can be carried out for the following:

MATERNAL INDICATIONS

- Post term pregnancy
- Pre labour rupture of membranes
- Gestational diabetes
- Abruption placenta
- Pre eclampsia/ eclampsia
- Intrahepatic cholestasis of pregnancy
- Maternal request
- Oligohydramnios
- Isoimmunisation
- Chorioamnionitis
- Chronic maternal condition (renal disease, pulmonary disease or anti phospholipid syndrome)

FETAL INDICATIONS

- Intrauterine fetal demise
- Fetal growth restriction

There are several factors that predict successful induction[15]. They include younger maternal age, multiparty, favourable cervix, body mass index < 30, estimated fetal weight less than 3500 grams. Induction is favoured by term pregnancy, increased sensitivity of the uterus assessed by positive

oxytocin sensitivity test, presence of fetal fibronectin (> 50 ng/ml) on vaginal swab is favourable for induction[16].

Positive factors for successful induction of labour

Period of gestation	Near tern or post term- more success
Pre induction score	Bishops score > 6 is favourable
Sensitivity of uterus	Positive oxytocin sensitivity test is favourable
Age	Younger maternal age
Parity	multiparous are favourable
Fetal Fibronectin > 50 ng/ml in vaginal swab	Favourable
Other factors	Estimated fetal weight < 3500

Assessment of cervix is done using the Modified Bishop scoring system that helps to select the appropriate method for induction of labor, and is used as a predictor of successful induction. A score of ≥ 6 is considered favorable, after which oxytocin is employed, and a score of less than 6 necessitates the need of cervical ripening[17].

The success of induction of labour is dependent upon the state of the cervix, and that with an unfavorable cervix, cervical ripening prior to induction is recommended.

Cervical ripening is done to soften the cervix that aids in its dilatation and thinning, which further increases the chances of a vaginal delivery. Cervical remodeling is an essential part of delivery process. It includes

changes in the collagen framework, changes in proteoglycans and increase in cytokine production[18].

Table 35.5: Bishop's Preinduction Cervical Scoring System (Modified)

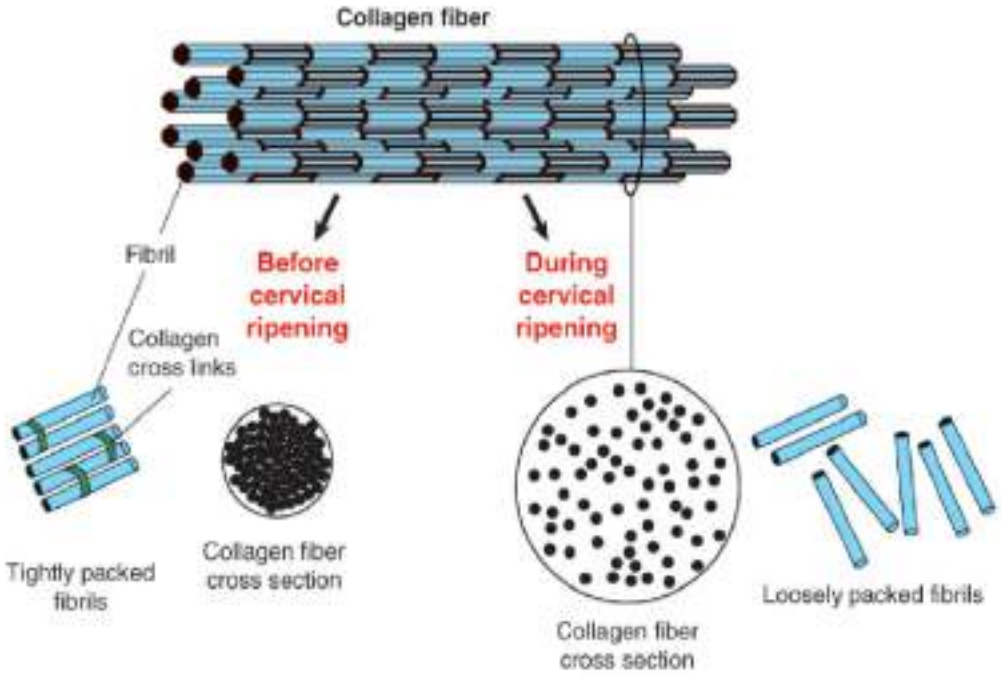
Parameters	Score			
	0	1	2	3
Cervix				
▪ Dilatation (cm)	Closed	1–2	3–4	5+
▪ *Effacement (%)	0–30	40–50	60–70	≥ 80
▪ Consistency	Firm	Medium	Soft	-
▪ Position	Posterior	Midline	Anterior	-
Head: Station	–3	–2	–1,0	+1, +2
Total score = 13; Favorable score = 6-13; Unfavorable score = 0-5				
*Cervical length (cm)	>4	2-4	1-2	<1

*Modification (1991) replaces effacement (%) with cervical length in cm.

Hegar in 1985, first described softening of the lower uterine segment at 4 to 6 weeks, a sign which was once used to diagnose pregnancy. Cervical softening results from increased vascularity, cellular hypertrophy and hyperplasia along with structural changes in the extracellular matrix. Collagen is the main structural protein of the cervix, which undergoes conformational changes that alter its flexibility. The number and type of covalent bond between the triple helix of collagen is altered. These changes begin in early pregnancy. However, before contractions begin, cervix must undergo extensive remodelling. This will result in cervix yielding and dilating in response to uterine contractions. Cervical modifications that help to achieve this, principally involving cervical connective tissue changes is termed at cervical ripening.

The transition from cervical softening to ripening occurs days before labour, due to changes in the matrix glycosaminoglycan's and proteoglycans. The collagen fibre architecture in cervix is reorganised to

allow an increase in mechanical compliance of the cervix. A collagen fibre is made up of many fibrils, during cervical ripening the fibril size is less uniform, and the spacing between the fibrils and fibres is increased, and is disorganised. High turnover of collagen during pregnancy allows replacement of mature collagen cross linked fibrils to immature disorganised collagen fibrils. This increased turnover of collagen helps to achieve cervical remodelling[19]. Depending on the state of the cervix, various methods can be used for cervical ripening in order to make the cervix more favourable.



Induction of labor is associated with certain risks, both to the mother and the foetus[16]. These include:

MATERNAL FACTORS

Increased operative interference

Prolonged labour

Increased need of analgesia

Abnormal uterine action

Tachysystole

Infection

Bleeding

FETAL FACTORS

Fetal hypoxia

Iatrogenic prematurity

The contraindications for use of any inducing agents are same, but not limited to those of vaginal delivery[5]. These include:

- Placenta previa/ vasa previa
- Cord prolapse
- Transverse lie or footling presentation
- Prior classical caesarean or T shaped uterine incision
- Previous myomectomy entering the endometrial cavity
- Active genital herpes infection
- Invasive cervical carcinoma
- Previous uterine rupture

METHODS OF LABOR INDUCTION

The various methods that can be used for induction are mentioned below:[16, 20-22]

NON PHARMACOLOGICAL METHODS

A. Traditional methods (no longer used)
    - castor oil
    - acupuncture
    - herbal remedies
    - nipple stimulation
    - sexual intercourse
B. Mechanical Methods:
    - Mechanical dilators
    - Foley's catheter
    - Trans cervical double balloon catheter

- Osmotic (hygroscopic) dilators, laminara tents
- Extra amniotic saline infusion

C. Surgical Methods
    - Stripping of membranes
    - Amniotomy (artificial rupture of membranes)

PHARMACOLOGICAL METHODS

- Oxytocin
- Prostaglandins (PGs)
    (i) Misoprostol (PGE1): tablets
    (ii) Dinoprostone (PGE2): gel, tablet, controlled release pessary
- Progesterone-receptor antagonists
  Mifepristone
- Relaxin
- Hyaluronic acid
- Estrogen

NON PHARMACOLOGICAL METHODS

A. Traditional methods: Traditional methods work by release of oxytocin from posterior pituitary (nipple stimulation) or by the release of naturally occurring prostaglandins. These methods are no longer used.

B. Mechanical methods: Methods such as trancervical placement of Foley's catheter with or without extra-amniotic saline infusion, mechanical or hygroscopic cervical dilators, laminara tents can be used for labor induction. These methods, when compared to oxytocin alone, had a lower cesarean delivery rate[23]. In comparison to prostaglandins, they have a lower chance of developing uterine tachysystole, however there is insufficient evidence of their efficacy when compared to prostaglandins[23].

C. Surgical methods

The surgical methods that can be used for induction of labour are

- Membrane stripping
- Amniotomy.

i. Membrane Stripping: It is a frequent practice done for induction of labor. It increases prostaglandin F2 alpha (PGF2 alpha) and phospholipase A2 activity. It increases the incidence of spontaneous labor, and reduces the need for induction with other methods[24]. It is also associated with maternal discomfort, risk of bleeding and an increased incidence of pre labor rupture of membranes.

ii. Amniotomy: Artificial rupture of membranes is often performed for accelerating labor. Amniotomy done at 5 centimeters, has shown to accelerate labor by 1 to 1 and ½ hours. There is insufficient evidence on the role of amniotomy alone for induction of labour[25]. Amniotomy along with oxytocin use is shown to shorten the induction to delivery interval as compared to amniotomy or oxytocin alone[26].

Amniotomy helps in labour augmentation by release of prostaglandins, it also helps in early detection of meconium especially in cases of non-reassuring fetal heart rate status. It helps in detection of abruption placentae by the presence of blood stained liquor and also accelerates labour in these cases. It helps to facilitate fetal cord blood sampling or fetal pulse oximetry.

For its use in labor induction, its use is unpredictable, and early amniotomy can increase the chances of chorioamnionitis. It also is associated with a risk of cord prolapse, to minimize this a fundal or supra pubic pressure is given, and it is performed at the time of uterine contraction.

PHARMACOLOGICAL METHODS:

The various pharmacological methods used for induction of labour are:

- Oxytocin

- Prostaglandins (PGs)
  (i) Misoprostol (PGE1): tablets
  (ii) Dinoprostone (PGE2): gel, tablet, controlled release pessary
- Progesterone-receptor antagonists: Mifepristone
- Relaxin
- Hyaluronic acid
- Estrogen

OXYTOCIN:-

Oxytocin was first described in 1948, by Theobald for its use in labour. A few years later it was used to stimulate uterine contractions[27]. Over the years many methods were then developed for induction of labour such as amniotomy, stripping of membranes, and prostaglandins.

Oxytocin is one of the most commonly used drugs. It has amino acid homology similar to arginine vasopressin and has significant anti diuretic action. Use of oxytocin for augmentation of labour is the key component in the active management of labour[28]. The goal of oxytocin use for induction or augmentation of labour is to produce sufficient uterine contractions in order to produce a cervical change and cause fetal descent. It is generally very successful to stimulate labor.

Dosage: - 10 units of oxytocin are usually diluted into a 1000 ml of solution, and administered by an infusion pump, this results in a concentration of 10mU/ml. An infusion pump allows precise control of flow rate. The bolus administration of oxytocin should be avoided, by attaching it into the main intravenous line close to the venipuncture site.

Regimens: - Both low dose (0.5-2 mU/ml) and high dose (4-6 mU/ml) can be used for labor induction and augmentation. Low dose regimens are less like to cause uterine tachysystole (> 5 contractions in a 10 minute period) with associated fetal heart rate changes[29-33].

Regimen	Starting Dose (mU/min)	Interval (min)	Incremental Increase (mU/min)
Low dose	0.5-1.5	15-40	1
	2	15	4,8,12,16,20,25,30
High dose	4	15	4
	4.5	15-30	4.5
	6	20-40[a]	6[b]

a= uterine tachysystole is common with shorter intervals

b= With uterine tachysystole and after oxytocin infusion is discontinued, it is restarted at one half the previous dose and then increased at 3 mU/min incremental doses

Oxytocin infusion is stopped on development of uterine tachysystole, which rapidly lowers the contraction frequency. This is because the half-life of oxytocin is 3 to 5 minutes, and a plasma steady state is reached in 40 minutes[5].

The adverse effects of oxytocin, although rare, include uterine rupture and water intoxication syndrome- which develops when aqueous fluids are administered in large amounts along with oxytocin. This can lead to convulsions, coma and even death. Hence, while administering high doses of oxytocin, its concentration should be increased, the flow rate should be kept constant.

PROSTAGLANDINS:

Prostaglandins can be divided into:

i. Misoprostol (PGE1): tablets
ii. Dinoprostone (PGE2): gel , tablet, controlled release pessary

i. Misoprostol (PGE1):

Misoprostol is a synthetic PGE1 analogue, which is approved for its use in peptic ulcer prevention. It is used ‘off-label’ for cervical ripening and induction of labor. It can be administered intra vaginally, orally, or sublingually. The vaginal administration of misoprostol offers an equal or superior efficacy for cervical ripening and induction of labor. It is available in a 100mcg or 200mcg tablet. According to the ACOG 2009, 25 mcg vaginal dose, which is one fourth of the 100 mcg tablet should be considered as the initial dose for cervical ripening and labor induction. It should be administered than every 3–6 hourly. The use of oxytocin should be after at least 4 hours after the last misoprostol dose[5].

In comparison to oxytocin, intracervical or intravaginal misoprostol, vaginal misoprostol is associated with an increased rate of vaginal delivery within 24 hours. Oral administration of misoprostol, also increases the chances of vaginal birth within 24 hours, as compared to a placebo[34-36].

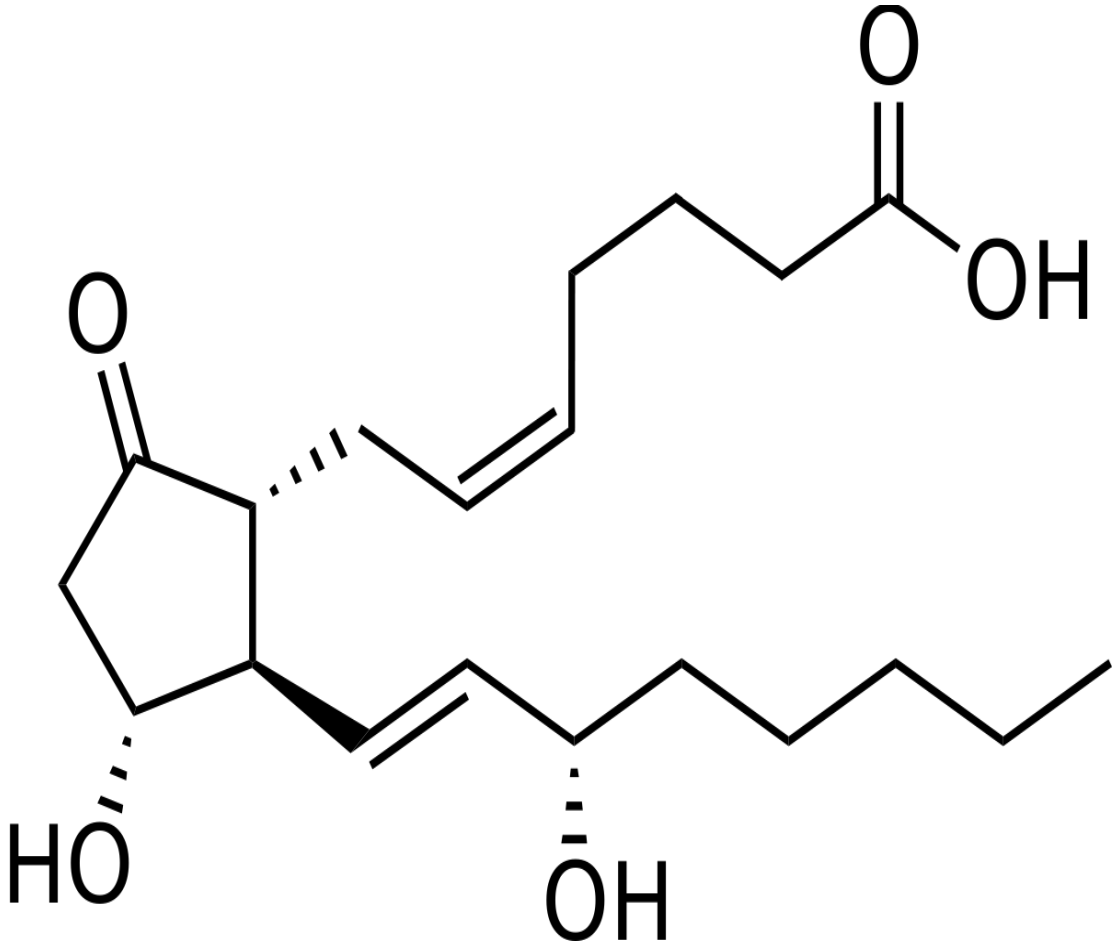
Higher doses of misoprostol (50 mcg every 6 hours) are associated with higher rates uterine tachysystole with or without fetal heart rate changes. The use of misoprostol in women with prior major uterine surgery has been associated with an increase in uterine rupture and should be avoided[37,38].

Misoprostol has a widespread use as an; off-label’ medical for cervical ripening and induction of labor, it is currently not approved for induction of labor by the Drug Controller General of India[9]. Further studies are required to determine its efficacy, safety and dosing frequency.

ii. Prostaglandin E2 (PGE2)

DINOPROSTONE:-

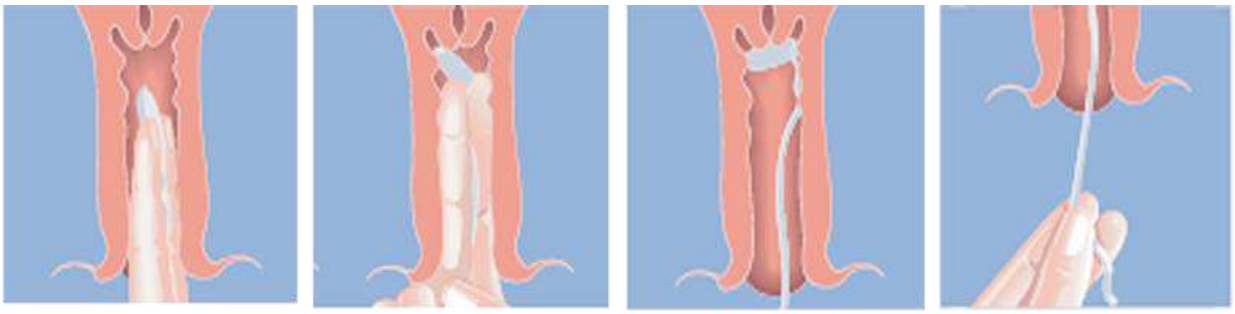
It is a synthetic analogue of prostaglandin E2. It has a molecular formula of $C_{20}H_{32}0_{5.}$ It has a molecular weight of 352.48 Dalton and a melting point of 65-68 degrees Celsius. Any PGE2 that enters the body is rapidly degraded by lungs, liver and kidney with a plasma half-life of 30 minutes.



Chemical structure of dinoprostone

For induction of labour, dinoprostone is available as a gel, vaginal tablet or a sustained release vaginal insert. It the preferred method of induction of labor, unless there are specific indications for not using it[10].

a. Dinoprostone gel: is available in a 2.5-mL syringe containing 0.5 mg of dinoprostone and a vaginal insert containing 10 mg of dinoprostone. It is placed intra cervically, with a prefilled syringe. The woman is asked to lie supine for a period of 30 minutes after insertion while the fetal heart rate is monitored. A maximum of 3 doses in 24 hours are recommended.
b. Dinoprostone vaginal insert: it has 10 mg dinoprostone, and releases prostaglandins at a rate of 0.3 mg/hr. it is placed transversely in the posterior fornix of the vagina.



1. Insertion
Holding the Propess® insert between the index and middle fingers of the examining hand, insert it high into the vagina towards the posterior vaginal fornix using only small amounts of water soluble lubricants.

2. Positioning
The index and middle fingers should now be twisted a quarter turn clockwise, pushing the Propess insert higher up, behind the posterior fornix and turning it through 90º so that it lies transversely in the posterior fornix.

3. After positioning
Carefully withdraw the fingers leaving the Propess® insert in the position shown in this diagram where it should remain *in situ*. After insertion ensure that the patient remains recumbent for 20-30 minutes to allow time for the Propess® insert to swell. Again, this will help it to remain in place for the duration of the treatment. Allow sufficient tape to remain outside the vagina to permit easy retrieval.

4. Removal
To stop prostaglandin E2 release, gently pull the retrieval tape and remove the Propess insert.

The fetal heart rate is monitored for 30 minutes post insertion. It is removed after 24 hours, it can be removed earlier if regular uterine contractions develop. Oxytocin induction usually follows dinoprostone, it should be started at least half an hour after the removal of dinoprostone pessary[9].

Side effects: - Uterine tachysystole can occur in 1 to 5 percent women following PGE2 insertion.

Uterine tachysystole: is defined as > 5 contractions in a 10 minute period. It can be associated with or without fetal heart rate changes.

Uterine hyper stimulation, hypertonus, and hypercontractility are terms no longer used[5].

In case of a dinoprostone 10 mg insert, it can be easily pulled out which will reverse the effect. Dinoprostone should be used with caution in patients with glaucoma, severe asthma, severe hepatic or renal

dysfunction, history of prostaglandin hypersensitivity and prior uterine surgery[39].

Other drugs such as relaxin, mifepristone and nitric oxide are being tried for induction of labour. Mifepristone antagonizes the effect of progesterone and increases the sensitivity of uterus to prostaglandins. According to Cochrane 2009, there is insufficient evidence to support the use of mifepristone in labour[40]. In addition, the use of hyaluronic acid appears beneficial for cervical ripening. However it is an invasive procedure and not commonly used.

There have been various studies comparing the different formulations of prostaglandins in the past. Initial studies were focused on clinical efficacy of prostaglandin E2 gel and misoprostol for cervical ripening and induction of labour[10]. The U.S. Food and Drug Administration (FDA) in 2002, approved a new label of misoprostol for use in induction of labour. This labeling neither claimed the efficacy and safety of misoprostol nor provide information regarding its various dosages. It is not approved by the drug controller general of India for induction of labour[5,9].

The PGE2 intravaginal sustained release pessary for IOL was licensed for use in June 2016 in India, since then limited studies are available comparing its efficacy with its gel/tablet forms.

According to the Cochrane review in 2014, a total of 70 studies (1,487 women) were evaluated. . Different preparations of prostaglandins (PGE2 gel, pessary and PGF2alpha) were compared with a placebo/ no treatment and a comparison was also made between the different formulations and their dosages. It was found that the use of vaginal prostaglandins (PGE2) increases the likelihood of successful vaginal delivery within 24 hours, as compared to a placebo. The rate of cesarean section was reduced by its use. (13.5% versus 14.8%, RR 0.91, 95% CI 0.81 to 1.02, 36 trials, 6599 women). Different formulations of prostaglandins (gel or sustained release pessary) appeared to be as effective as each other, the differences between them being small. The

risk of hyper stimulation was increased with use of prostaglandin analogues for IOL. (4.8% versus 1.0%, risk ratio (RR) 3.16, 95% confidence interval (CI) 1.67 to 5.98, 15 trials, 1359 women)[41].

A critical analysis was done by William F. Rayburn in 1989. A total of 59 clinical trials were conducted in which 3313 patients were evaluated to study the effects of intracervical or intravaginal administration of prostaglandin E2 gel on cervical ripening and IOL. After local PGE2 gel administration, the changes in bishop's score, induction to delivery interval, need of oxytocin were noted. The presence of any adverse effect and maternal hyper stimulation was looked for. This study concluded that use of PGE2 gel reduced the induction to delivery interval, reduced the need of cesarean section, and reduced the need for oxytocin. The uterine hyper stimulation was noted in < 1 % cases, no significant maternal and fetal adverse events were noted. Hence, it showed that the use of prostaglandins (PGE2) for cervical ripening was superior to placebo, and was associated with a favorable outcome[42].

A meta-analysis was done by Sanchez et all (1997), in which the efficacy of misoprostol for cervical ripening and induction of labour was studied. A total of 16 studies (eight of which were included) were evaluated. Out of the total 966 patients, 488 patients were administered misoprostol vaginally and 478 patients were taken as controls. Each clinical trial was analyzed for randomization, inclusion and exclusion criteria, dosages of misoprostol use, blinding and method of misoprostol administration. The need for oxytocin use, achievement of vaginal delivery in 24 hours, cesarean rates, and Apgar scores were evaluated. The data collected was analyzed using the fixed effects and random model. The results showed that, women who received misoprostol had a g higher rate of vaginal delivery achieved within 24 hours (OR 2.64, 95% CI 1.87, 3.71), the induction to delivery interval was lower (95% CI -3.5, -5.7) as compared to the control group. The cesarean rate in misoprostol group was lowered (OR 0.67, 95% confidence interval ICI] 0.48, 0.93). The risk of uterine

tachysystole was higher in the misoprostol group (95% CI 0.98, 3.73). There were no significant differences in Apgar scores between both groups[43].

In a study conducted in 2002, Mukhopadhyay et al compared the cost effectiveness of dinoprostone pessary and gel for induction of labor in nulliparous women. Nulliparous women with vertex presentation, singleton pregnancy, bishops score <6, were randomly given prostaglandin gel or pessary. 50 women received gel, 45 women received propess pessary. The propess was removed after 12 hours, or earlier in case of rupture of membranes, development of good uterine contractions, or any signs of fetal compromise. In both groups, a vaginal examination was done after 12 hours, modified bishops score was calculated, and amniotomy was performed. A second dose of prostaglandin: gel or pessary was administered according to the clinician's choice if cervix remained unfavorable after 12 hours. Different parameters were assessed to evaluate the cost effectiveness- the number of doses of prostaglandins needed, the number of visits to ward, number of vaginal examinations and pain relief. 53% patients in pessary group required more than one dose of prostaglandin preparation , as compared to 34% patients in the gel group, p value=0.03. There were no statistically significant differences between the mode of delivery, need of oxytocin, need for epidural analgesia, and number of visits to ward or the number of vaginal examinations between the two groups. Thus, the pessary did not seem to have an additional advantage, in terms of cost effectiveness over the gel group for induction of labor in nulliparous women[44].

The NICE clinical guidelines, released in July 2008, emphasized the use of prostaglandin E2, either as a gel, tablet or sustained release pessary.as the preferred method for induction of labour. This led to further studies being done to compare the efficacy and safety of different forms of prostaglandin (PGE2) preparations available. It was done to identify the most suitable agent to be used for cervical ripening for induction of labour

in women in regard to parity, maternal and gestational age and the presence of any fetal or maternal complicating factors[10].

A study conducted by Kalkat et al. in 2008, was done to compare the clinical efficacy of dinoprostone intracervical gel with slow release pessary for induction of labor (IOL). A total of 120 women were randomly allocated into the two groups: one group received intracervical gel, the other group received sustained release pessary. The study aimed to evaluate efficacy and cost-effectiveness of the two groups. The results showed that the number of vaginal deliveries within 24 hours of induction in the pessary group were 63.3% , as compared to gel 66.6%, (p value is 0.71), the induction to delivery interval in the pessary group was 22.9 hours+/-12.7 versus gel group 20.3 hours+/-11.4, with p value =0.23. The cesarean rate in pessary group was 13%, gel group was 23 % (p value=0.23), need for oxytocin augmentation in pessary group was 37 %, gel group was 38% (p value=1). There were no statistically significant differences in the above findings. However, the number of vaginal examinations in pessary group (5.0 +/- 2.2) and gel group were (6.2 +/- 2.7) with p=0.012. This difference was marked in primigravidas (p= 0.011) cost effectiveness in terms of amount of drug used, and number of midwifery hours were compared. It was found that the pessary was more cost effective than the gel. The study concluded that both the drugs were equally efficacious for IOL, in terms of vaginal delivery rate and the induction to delivery interval. The dinoprostone pessary, in addition was associated with a lesser number of vaginal examinations; especially in primigravidas; and appeared to be more cost effective as compared to that of the gel[45].

Kho et al carried out a retrospective study in 2008, to compare the efficacy and safety of dinoprostone sustained release pessary with intracervical gel for IOL. In this study, 969 women were induced, 507 women received dinoprostone pessary and 462 women received intracervical gel for induction of labour. The Induction to delivery interval, the mode of delivery, need of oxytocin and presence of uterine hyper stimulation were

compared in both the groups. The Induction to delivery interval was found to be longer in a nulligravida receiving the pessary than that of the gel. (21.5 vs 17.8, P= 0.004). There were no such differences in multiparous women (15.4 versus 14.2 hours, p=0.15). Uterine hyper stimulation was more in the women with the pessary (22 (4.5%) vs 11 (2.4%) relative risk (RR) 1.9 (0.9–3.8)), as compared with intracervical gel. The need for oxytocin for augmentation in nulligravida (66.5%in pessary versus 59.9% with gel, p=0.10), in multigravida (44.6% in pessary and 40% in gel, p=0.37) or the mode of delivery in nulliparous, p value=0.3, multiparous p value=0.2), were not statistically significant. To conclude, there seemed to be no added advantage for the women receiving the intravaginal pessary as compared to the gel group, furthermore the rate of hyper stimulation was increased in the pessary group as compared with that of the gel[46].

Triglia et al, 2010 compared the clinical efficacy of 24-hour vaginal dinoprostone pessary compared to gel for induction of labor in women with unfavorable cervix. It was one of the first prospective randomized trial comparing the dinoprostone vaginal insert versus gel in patients admitted for IOL with an unfavorable cervix. A total of 133 women, with Bishops score < 4 were enrolled. They were randomly administered either a dinoprostone controlled release vaginal pessary or a dinoprostone gel. Both multiparous and nulliparous women were equally present in the study. Out of all the patients, the incidence of spontaneous vaginal delivery in the pessary group was 72% which was higher than gel group 54%. (p value = 0.03). The cesarean section rate in gel group was 25% versus pessary group was 31% (p value =0.43), the rate of operative vaginal delivery was 3% in pessary group, 15% in gel group (p value =0.02). The induction to delivery interval had a p value = 0.36, which was not statistically significant. No episodes of hyper stimulation were present in either group, and there were no significant maternal and fetal side effects, no difference between the Apgar scores between the two groups were seen. To conclude both the methods appeared to be safe for

induction of labour, the dinoprostone pessary form was associated with a significantly higher rate of vaginal delivery and a lower rate of operative vaginal delivery as compared to the gel form. No difference in the cesarean section rates was noted[47].

Facchinetti et al in 2012 conducted a meta-analysis assessing the safety and efficacy of dinoprostone vaginal insert as compared to repeated prostaglandin administration (PGE2 and PGE1). The nulliparous and/or multiparous women with unfavorable cervix (Bishop <5) and intact membranes were included in the study. 18 RCTs, including seven studies (911 women) were meta analyzed. . The primary outcome measured was the cesarean section rate. Out of all participants, the rate of cesarean section in nulliparous women who were offered an intra vaginal insert was 24%, which was lower than other forms of prostaglandin use. (RR = 0.76, 95% CI = 0.59, 0.98). No difference was found in multiparous women. (RR=0.77, 95%CI = 0.60.2.61) The use of oxytocin with patients with vaginal insert was lower (RR =0.64, 95% CI = 0.42, 0.99), rate of vaginal delivery in nulliparous was (RR=1.09, 95%CI=1.00-1.20), multiparous was (RR=1.03, 95%CI=0.93, 1.14), rate of uterine hyper stimulation, was reported to be higher in the pessary group (RR = 2.17, 95% CI = 1.08, 4.33). To conclude , the use of vaginal insert was associated with less oxytocin use and more vaginal deliveries in nulliparous women, as compared to other forms of prostaglandins, but is associated with a higher hyper stimulation rate[48].

Tathem et al, in 2012 evaluated the safety of dinoprostone sustained release pessary was for its 24 hour use. A total of 269 consecutive nulliparous patients, who were > 37 weeks of gestation, with vertex presentation and had bishops score <4 were selected. They were administered the intravaginal pessary, which was left in place for a 24 hour period. It was removed if uterine tachysystole developed which is > 5 contractions in a 10 minute interval with or without FHR changes. The frequency of uterine tachysystole was recorded in the first 12 hours and

the second 12 hours of the pessary use. Morbidity outcomes such as Apgar scores, maternal nausea, postpartum hemorrhage, maternal diarrhea, nursery admission were recorded. Pearson Chi-squared analyses and Kaplan–Meier analysis were performed. Maternal adverse events such as postpartum hemorrhage was seen in 17.2% women within 12 hours of use, and 18.4% women within 24 hours of use, p value=0.83. Rise in intra partum temperature>37.8 degrees Celsius was seen in 6.1% women within first 12 hour of use, and 6.9% women within 24 hour use (p value=0.82). Apgar score at one minute </= 6, was seen in 14.1% women after 12 hours of use, and in 9.2% women after 24 hours of use (p value=0.30), the number of admissions to neonatal intensive care unit were in 29.3% women within 12 hours of use, and 27.6% patients within 24 hour use of pessary (p value=0.80) Out of all patients, uterine tachysystole occurred in 25 (9.3%) women, with 68% within first 12 hours of use. With its mean duration being 10 hours. 93% of the uterine tachysystole resolved after one hour of removal of the pessary. There were no significant differences between the maternal and neonatal morbidity factors. This study concluded, that the intra vaginal insert kept for 24 hours was a safe method for IOL, as its 12 hour use. This study was the largest study done till date evaluating the safety parameters for dinoprostone pessary for induction of labour[49].

In 2015, Kandemir et al conducted a retrospective study to evaluate the effect of parity on cervical ripening in patients undergoing induction with dinoprostone intra vaginal pessary. A total of 2090 women, including 1172 nulliparous, and 918 multiparous women were enrolled in the study. All patients received a 10 milligram sustained release dinoprostone pessary, placed transversely in the posterior fornix. The pessary was removed 24 hours, it was removed earlier if regular painful uterine contractions developed, accounting for 2 to 3 contractions in 10 minutes. The primary outcome measure was the induction to delivery interval. Other measures were cesarean section rate, need of use of oxytocin, uterine hyper

stimulation, any neonatal or maternal adverse events. The treatment was said to be successful if vaginal delivery occurred within 24 hours of induction. The mean maternal age was 25.22+/-4.9, gestational age was 40.21+/-1.2, bishops score prior to induction was 2.47+/-0.2. Out of all patients, vaginal delivery within 24 hours occurred in 65.7% nulliparous females, 75.1% multiparous females (p value=0.001), rate of cesarean delivery was 34.3% in nulliparous, 24.9% in multiparous females (p value=0.002), need for oxytocin for augmentation of labor was seen in 34.9% nulliparous females, and 26.4% of multiparous females (p value= 0.001). The rate of hyper stimulation, differences in Apgar scores were not significant between the two groups. The change in bishops score was higher in nulliparous women, p value= 0.034. To conclude, the multiparous women who received dinoprostone pessary for induction of labor, had a shorter labor, delivered early, had lower rates of cesarean section and less need for oxytocin use as compared to nulliparous women. The change in bishops score was more in nulliparous women as compared to multiparous women[50].

A retrospective study was conducted by Zhao et al in 2017, various factors associated with vaginal delivery in patients induced with dinoprostone insert were studied. 1656 women were induced with dinoprostone vaginal insert, out of which 396 (23.91%) women delivered by cesarean section, 1260 (76.09%) had vaginal delivery. Various factors associated with vaginal delivery within 24 hours were studied. Multiparity p<.001, OR=8.74, 95%CI 4.36–17.50), was seen to be a positive factor for vaginal delivery, maternal age at time of delivery, birth weight (p<.001, OR=0.37, 95%CI 0.28–0.51) baseline fetal heart rate (p=0.004, OR=0.96, 95%, CI 0.94–0.99) were strongly correlated with vaginal delivery within 24 hours. The bishop score of patients enrolled in the study was between 4 to 5, which showed no effect on attainment of vaginal delivery (p value=0.11) which was not significant. To conclude, maternal age and birth weight were significant predictors of vaginal delivery[51].

Devdatt L. Pitale in 2017 also studied the effectiveness of dinoprostone vaginal pessary for induction of labour at term. 20 pregnant women at > 37 weeks of gestation, with bishop's score< 6, and who were fulfilled the inclusion criteria were taken. The dinoprostone pessary was inserted in the posterior fornix of these patients. Out of all the patients that were induced, 70% cases resulted in a spontaneous vaginal delivery. The average induction to delivery interval was found to be 18 hours. No maternal or neonatal adverse event was noted. It was found that the number of vaginal examinations was reduced significantly. To conclude, dinoprostone pessary helped in limiting the spread of ascending infections and reducing maternal anxiety by significantly reducing the number of pelvic examinations, at the same time it is highly effective for induction of labour at term[52].

Swati et al conducted the first known study for publication in India in 2018. It was a prospective randomized controlled study, done to compare the efficacy of PGE2 sustained release vaginal pessary and intracervical gel for Induction of labour. 200 patients selected for induction were offered intracervical pessary and gel alternatively. They were divided into two groups after fulfilling the inclusion and exclusion criteria based on the preparation of dinoprostone used. Relevant data was collected, including demographic data, indications of Induction of labour, changes in bishop score at 6, 12 and 24 hour. Timing from induction to delivery interval, need of oxytocin use, maternal and neonatal outcome was noted. Achievement of uncomplicated vaginal delivery was the primary outcome measure. Out of 200 total patients enrolled for the study, 71% delivered vaginally and 29% underwent cesarean section in the pessary group, and 63% delivered vaginally, 37% underwent cesarean section in the gel group (p value=0.229), induction to delivery interval in between both groups was not significant, p value=0.299. The need of oxytocin augmentation in pessary group was 51% and gel group was 72% with p value = 0.002.

The change in bishops score at admission, and after 6 hours was not significant, 23 women in pessary group developed fetal adverse events, as compared to 22 people in the gel group.(p value=0.866). Hyper stimulation was not noted in either of the groups. It was concluded that the only statistically significant difference between the two groups was the need of oxytocin use which was significantly higher in the intracervical gel group[53].

In 2018, Ishaqui et al conducted a prospective cohort observational study in primigravida women, to compare the use of vaginal tablet and vaginal insert for induction of labour. A total of 135 patients, with Bishops score less than 6 were taken. 82 (60.8%) were given dinoprostone tablets , placed in posterior fornix every 6 hourly, for a maximum of 3 doses, and remaining 53 (39.2%) patients received a dinoprostone vaginal insert. Data was analyzed using the chi-square statistical analysis. Statistically, no significant differences were found in the cesarean section rates between two groups. The incidence of cesarean section was 36% with tablet form and 34% with the insert form (p value = 0.576), the rate of spontaneous delivery was 42.7% in tablet form, and 45.3% with the pessary (p=0.766). Instrumental delivery rate was 20.7% in tablet form and 20.8% in pessary form (p=0.997), average length of labour was 7 hours (2-12) in tablet form, and 6 hours (3-12) in pessary form (p=0.616).These values were not of statistical significance. No significant difference were found in maternal and fetal adverse events or hyper stimulation. To conclude, both tablet and pessary forms of dinoprostone were found to be equally efficacious for induction of labour in primigravida women[54].

In another comparative study by Kumari et al in 2018, the outcome of induction of labour in primigravidae with gel as compared to pessary was studied. Nulliparous women with unfavorable cervix (Bishop <6) and intact membranes were enrolled for the study, planned Induction of labour was done, a dinoprostone pessary or an intracervical gel was placed after

initial assessment, followed by continuous FHR monitoring for one hour. Failure of induction was defined as failure to achieve cervical dilation of > 4 cm despite 10 hours of titrated oxytocin infusion. A total number of 166 women were included in study, 88 in gel group and 78 in pessary group (n=76). The baseline characteristics including maternal age, mean gestational age, modified Bishop's score were similar in both the groups. The comparison between the two groups was done using the chi-square analysis and contingency table and t-test.

The p-value of 0.05 or less were considered significant. Out of the total patients, 2 patients in gel group. And 6 patients in propess group had failed induction. Which was not statistically significant (p= 0.51), 24 (27.3%) underwent cesarean section in gel group, 32 (14.1%) patients underwent cesarean section in pessary group (p value=0.24), rate of instrumental delivery in gel group 28 (31.8%), and pessary group 8 (10.5%) with p value=0.04, the mean time taken to deliver in gel group was 21.1 hours, and in pessary group was 29.6 hours with p value=0.02. To conclude, no statistically significant differences in the cesarean section rates, rate of spontaneous vaginal delivery, or need of oxytocin use was found between the two groups. It was seen that the gel group resulted in a quicker delivery, although had higher rates of instrumental delivery than the pessary group, which had higher chances of hyper stimulation[55].

Eriksson et al in 2020 conducted a prospective cohort study to compare the safety and efficacy of low dose preparations of misoprostol for induction of labour. Nulliparous women who were candidates for vaginal delivery were included in the study. One group used 25 mcg oral misoprostol tablets and the other used slow release misoprostol vaginal insert for induction of labour. Delivery within 24 hours, caesarean section rate, and rate of uterine hyper stimulation were noted. It was seen that there was a significantly higher rate of uterine tachysystole with the vaginal route (28.4% compared with 2.3%). No differences were found in neonatal asphyxia in both the groups. Patients with vaginal route had a

quicker delivery than the tablet form (65% versus 22%). This showed that the vaginal form resulted in a quicker delivery with increased rates of uterine hyper stimulation, whereas the tablet form appeared to be safe[56].

Wise et al in 2020, conducted a randomized controlled trial to evaluate the effectiveness, safety and cost effectiveness of inpatient vaginal prostaglandin E2 administration and an outpatient balloon catheter insertion. Pregnant women with singleton pregnancy, more than 37 weeks gestation, with bishops score less than 7 selected for induction of labour were enrolled in the study. Patients with previous caesarean section or those with maternal or fetal risk factors for whom outside patient care would be risky were excluded. After performing a vaginal or a per speculum exam, a single balloon catheter was placed above the internal os inflated with 50 ml sterile saline. Women was discharged and asked to return 18-24 hours of placement. On admission, artificial rupture of membranes was done or prostaglandin was administered.

In the inpatient group, a dinoprostone gel or pessary was placed in the vagina. After 6 hours (for gel) or after 12 to 24 hours for pessary, the artificial rupture of membranes was done or a repeat dose of prostaglandins was administered. It was found that the outpatient balloon catheter reduced caesarean section rates, was cost effective, safe and more acceptable for use[57].

MATERIAL AND METHODS

The study was conducted in the Department of Obstetrics and Gynaecology, Dayanand Medical College and Hospital, which is a tertiary care hospital.

This is a prospective randomized study conducted over one a period of one year starting from 1st January 2019 and followed till 31st December 2019.

INCLUSION CRITERIA:

Study population consisted of both Booked/Un-Booked antenatal cases of gestation 37 weeks or more, with singleton pregnancy, vertex presentation, with Bishops score <6.

Both primigravidas and multigravidas were included in the study.

EXCLUSION CRITERIA:

1. Subjects with multiple pregnancy
2. Gestational age less than 37 weeks
3. Fetal presentation other than vertex
4. Having undergone previous uterine surgery (myomectomy, caesarean section)
5. Fetal distress
6. Patients with any contraindication to vaginal delivery or contraindication for labour induction by prostaglandin or oxytocin
7. Presence of uterine activity
8. Active vaginal bleeding

METHOD:

The study was conducted on booked/unbooked pregnant women > 37 Weeks of gestation admitted in the antenatal ward of Dayanand Medical College and Hospital for induction of labour. A total of 100 patients were enrolled in the study. After admission a detailed history, systemic and obstetric examination was done. A per vaginal examination was done, under all aseptic precautions and the modified bishops score for each patient was calculated. Routine investigations were done.

Patients with Modified bishops score less than 6 were selected for induction and those who fulfilled the inclusion and exclusion criteria were divided into two groups (group A and B). The patients were randomly distributed between the groups. Informed consent for induction of labor was taken. Non stress test was done before induction.

Group A: Patients in this group received a single dose of 10 mg slow release dinoprostone vaginal insert placed transversely in posterior fornix of the vagina. The patients were assessed after 24 hours, the modified bishops score was calculated, and the intravaginal insert was removed. It was removed earlier if patient developed good intensity uterine contractions (5 contractions or less in 10 minutes averaged over a 30 minute window). Induction was considered successful if the MBS > 6 after 24 hours of its insertion.

Group B: Patients in this group received an instant release gel preparation containing 0.5 mg of dinoprostone, placed intra cervically. The patients were assessed every 6 hours, and the modified bishop's score was calculated. If a Bishops score was less than 6, a second was repeated. A maximum of three doses were given. Induction was considered successful if MBS > 6 after 24 hours of start of induction.

All the patients were instructed to lie down for half an hour after insertion, after which they were allowed to be ambulatory. They were instructed to note the expulsion of the pessary. The patients in whom induction was successful, were further subdivided into two groups.

The patients with successful induction in Group A formed Group C.

The patients with successful induction in Group B formed Group D.

These patients were assessed for the need of oxytocin. Continuous electronic fetal heart monitoring was done for all patients. A partograph was plotted, the patients were followed till delivery and the maternal and neonatal outcomes were assessed. Adverse events were noted in both groups. In case of adverse events, pessary was removed and adequate measures were taken in patients induced with gel.

The following outcomes were studied for both groups:

1. **Demographic parameters**
    - Age
    - Socio-economic status
    - Antenatal Care
2. **Maternal parameters**
    - Period of gestation at which induction was carried out
    - Gravidity
    - Mode of delivery
3. **Induction of labour**
    - Indications for induction
    - Modified bishops score and outcome of induction
    - Successful induction
    - Comparison of maternal demographic parameters of successful induction
    - Need of oxytocin
    - Time interval between instillation of drug to onset of good uterine contractions
    - Time interval between instillation of drug to delivery
    - Adverse events
    - Number of per vaginal examinations
    - Patient satisfaction score
4. **Fetal parameters:**
    - Live birth
    - Fetal sex
    - Fetal birth weight
    - Apgar score
    - Admission to NICU
    - Indication of admission to NICU

The number of vaginal examinations was assessed from start of induction till delivery. Patient satisfaction was analyzed on a scale of 0 to 10. With 0 being the lowest level of satisfaction to 10 being the highest.

STATISTICAL ANALYSIS

The data collected in respect of various variables was analyzed by using different statistical techniques which included T-test, Fischer's extract test, Chi square test

Statistical analysis included T-test and Chi Square Test.

OBSERVATION AND RESULTS

In our study a total of 100 pregnant patients for induction of labour were taken.

Patients were randomly divided into two groups according to the preparation of drug used.

Those who received the intra vaginal insert formed the study group A, those who received intracervical gel formed group B.

Group A(n) = 56

Group B(n) = 44

DEMOGRAPHIC PARAMETERS

The demographic parameters in this study are:

1. Age
2. Socio-economic status
3. Antenatal Care

1. Age

Table 1: Mean age of women in group A and group B.

	Group A (n=56)		Group B (n=44)		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
AGE	28.75	3.80	28.77	2.80	0.033	0.974	-1.33	1.38

In our study the mean age in the group A and B was 28.75 years and 28.77 years respectively. This was was not statistically significant (p value was 0.97) .

Table 2: Age wise distribution between group A and group B.

	AGE	Group A n=56	(%)	Group B n=44	(%)	Total	Chi-square value	p-value
Age	21-25	12	21%	6	14%	18	1.014	0.314
	26-30	30	54%	27	61%	57	0.610	0.435
	31-35	11	20%	11	25%	22	0.412	0.521
	35-40	3	5%	0	0%	3	2.430	0.119
Total		56	100%	44	100%	100		

Out of 56 patients in group A, 12 (21%) belonged to the age group of 21-25 years, 30 (54%) patients belonged to the age group of 26-30 years, 11 (20%) patients belonged to the age group of 31-35 years and 3 (5%) patients belonged to the age group of more than 35 years.

Out of 44 patients in group B, 6 (14%) patients belonged to the age group of 21-25 years, 27 (61%) patients belonged to the age group of 26-30 years, 11 (25%) patients belonged to the age group of 31-35 years and there was no patient in the 35-40 years age group. a majority of patients belonged to 26-30 years in both the groups. There was no statistically significant difference between the two groups.

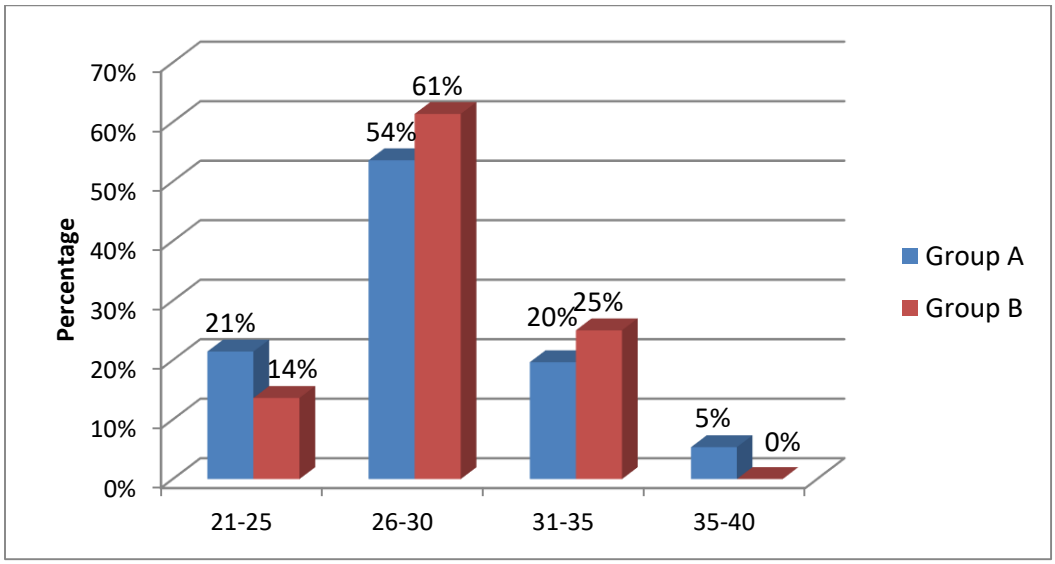


Figure 1: Distribution of patients according to their age groups.

2. Socio-Economic Status

Table 3: Distribution of patients according to their socio-economic status.

		Group A		Group B		Total	Chi-square value	p-value
		n=56	%	n=44	%			
Socio-Economic Status	Lower	18	32%	13	30%	31	0.170	0.919
	Middle	17	30%	15	34%	32		
	Upper	21	38%	16	36%	37		
Total		56	100%	44	100%	100		

Patients in both the groups were divided according to their socioeconomic status using the modified kuppuswamy scale. The scale graded the patients according to their education, occupation and income. Patients with scores less than 10 were classified as lower socio-economic class, while patients with score from 10-25 were classified as middle socio-economic class, and patients with score from 26-29 were classified as upper socio-economic class.

In group A, 18 (32%) patients belonged to lower socioeconomic class, 17 (30%) patients belonged to middle socio-economic class , while 21 (38%) patients belonged to upper socio-economic class.

In group B, 13 (30%) patients belonged to lower socio-economic class, 15 (34%) patients belonged to middle socio-economic class and 16 (36%) patients belonged to upper socioeconomic class . A majority belonged to upper socioeconomic status in both the groups.

There was no statistically significant difference between the two groups in all the classes. The p value being 0.919 .

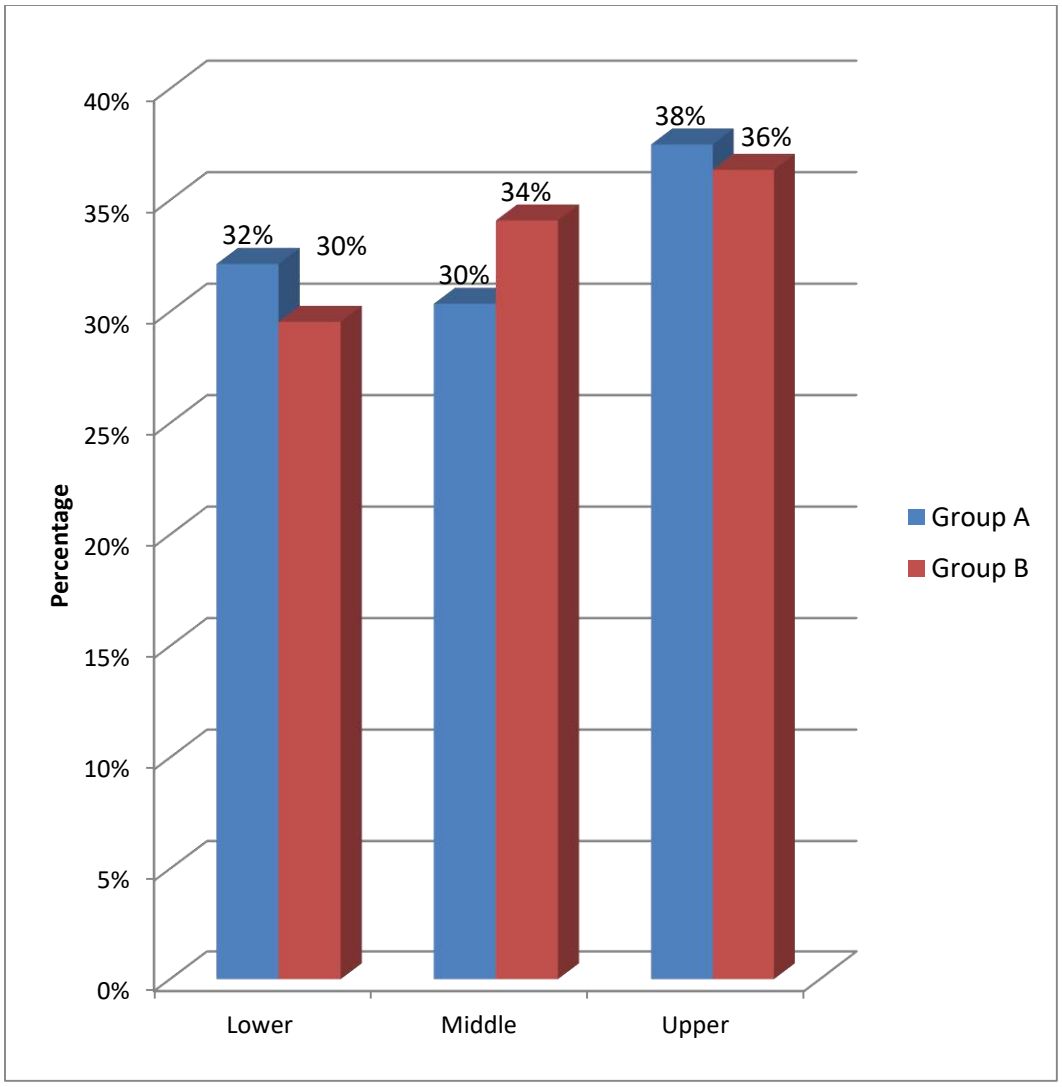


Figure 2: Distribution of patients according to their socio-economic class.

3. Antenatal Care

Table 4: Distribution of patients according to the antenatal care they received.

		Group A		Group B		Total	Chi square value	p- value
		n=56	(%)	n=44	n=44			
Booked / Unbooked	Booked	46	82%	31	70%	77	1.901	0.168
	Unbooked	10	18%	13	30%	23		
Total		56	100%	44	100%	100		

Out of a total 100 patients, 82% (n=46) were booked and 18% (n=10) were unbooked whereas 70% (n=31) were booked and 30% (n=13) were unbooked patients in Group A and Group B respectively. A majority of the patients were booked patients in both the groups. There was no statistically significant difference between the two groups (p value being 0.168).

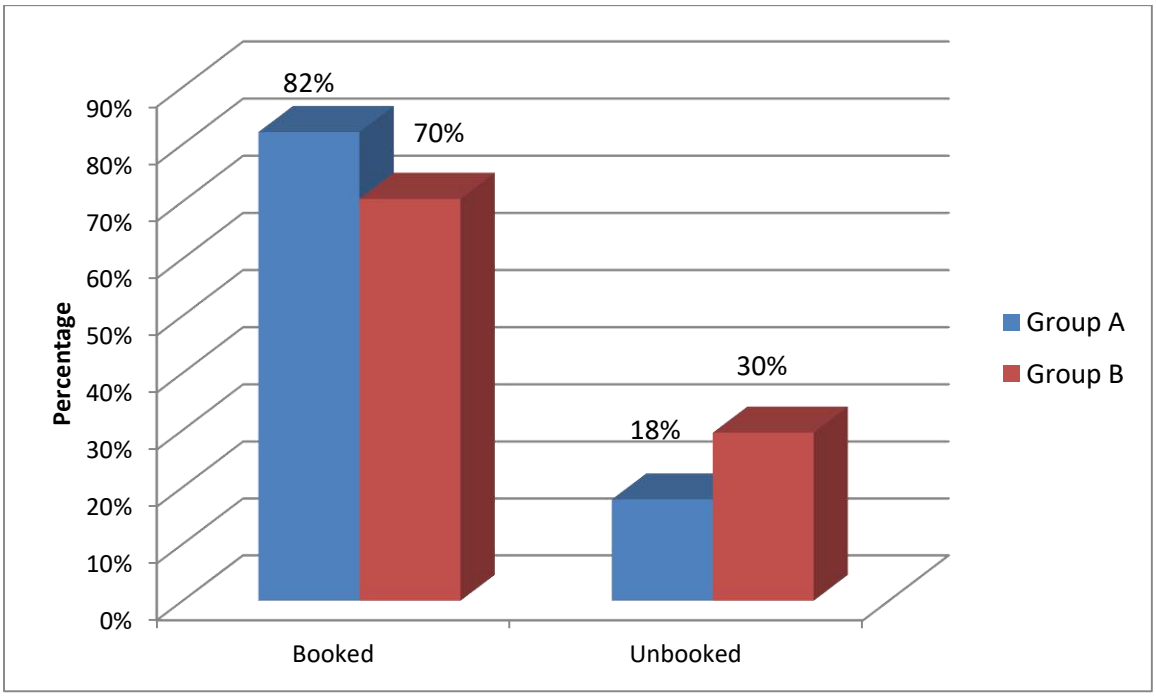


Figure 3: Distribution of patients according to the antenatal care they received.

MATERNAL PARAMETERS

The maternal parameters under study for all groups are:

1. Period of gestation at which labour was induced
2. Gravidity
3. Mode of delivery

1. Period of gestation at which labour was induced

Table 5: Distribution of patients according to the period of gestation at which labour was induced.

		Group A		Group B		Total	Chi-square value	p-value
		(n=56)	(%)	(n=44)	(%)			
Gestation	37-37+^{6}	19	34%	16	36%	35	0.064	0.800
	38-38+^{6}	17	30%	12	27%	29	0.114	0.736
	39-39+^{6}	11	20%	12	27%	23	0.810	0.368
	> 40	9	16%	4	9%	13	1.062	0.303
Total		56	100%	44	100%	100		

In group A, 34% (n=19) were induced at 37-37+^{6} weeks, 30% (n=17) patients were induced at 38-38+^{6} weeks, 20% (n=11) were induced at 39 to 39+^{6} weeks and 16% (n=9) were induced at gestational age of equal to or more than 40 weeks.

In group B, 36% (n=16) were induced at 37-37+^{6} weeks, 27% (n=12) were induced at 38-38+^{6} weeks, 27% (n=12) were induced at 39-39+^{6} weeks and 9% (n=4) patients were induced at a gestational age of more than 40 years. A majority were induced between 37 - 37+^{6} weeks period of gestation in both the groups.

There was no statistically significant difference between the groups. (p value was more than 0.005 in all groups)

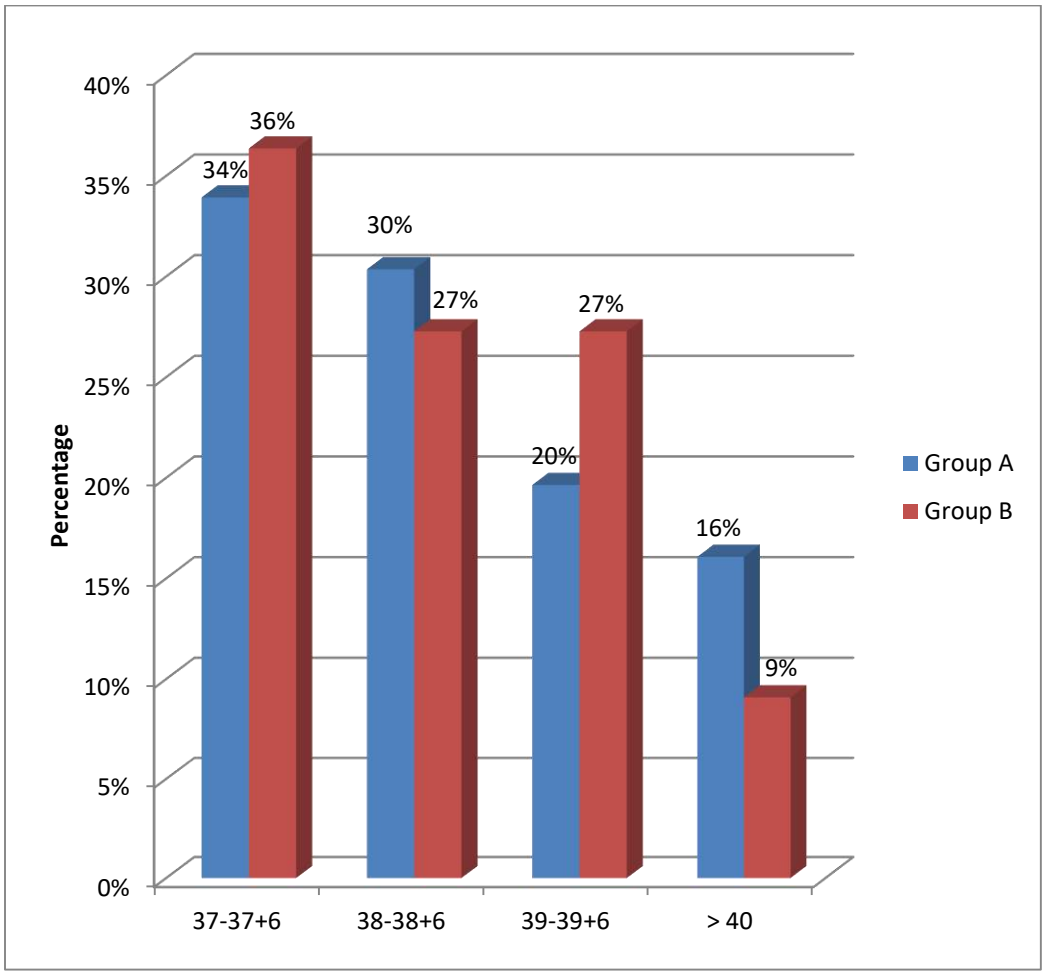


Figure 4: Distribution of patients according to the period of gestation at which labour was induced.

2. Gravidity

Table 6: Distribution of women under study according to gravidity.

		Group A		Group B		Total	Chi-square value	p-value
		n=56	%	n= 44	%			
GRAVIDA	Primi	48	72%	19	28%	67	20.160	0.001
	Multi	8	24%	25	76%	33		
Total		56	56%	44	44%	100		

In group A, 72% (n=48) women were primigravida and 24% (n=8) women were multigravida. In group B 28% (n=19) were primigravida and 76% (n=25) were multigravida. There was statistically significant difference between the two groups (p value was 0.001).

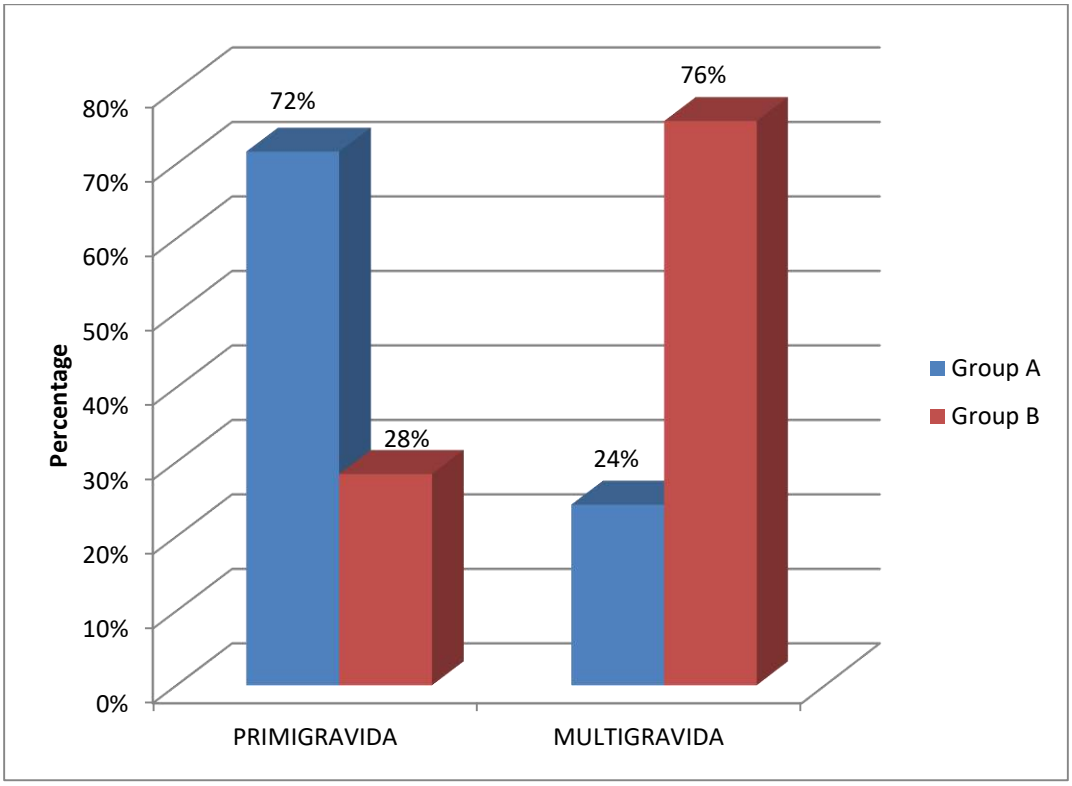


Figure 5: Distribution of women under study according to gravidity.

3. Mode of delivery

Table 7: Distribution of patients according to the methods of induction of labour and the mode of delivery.

	Group A		Group B		Total	Chi-square value	p-value
Mode of delivery	n=56	(%)	n=44	(%)			
Vaginal delivery	29	52%	27	61%	56	0.917	0.338
Instrumental delivery	2	4%	4	9%	6	1.331	0.249
Cesarean section	25	45%	13	30%	38	2.384	0.123

Fifty two percent (n=29) patients in group A underwent vaginal delivery 45% (n=25) patients underwent cesarean section, and 4% (n=2) patients underwent instrumental delivery. In group B, 61% (n=27) patients underwent vaginal delivery, 30% (n=13) patients underwent a caesarean section. Nine percent (n=4) patients underwent instrumental delivery and 30% (n=30) patients underwent cesarean section. A majority of patients had vaginal delivery in both the groups. The p value in these groups was not statistically significant (p value > 0.005).

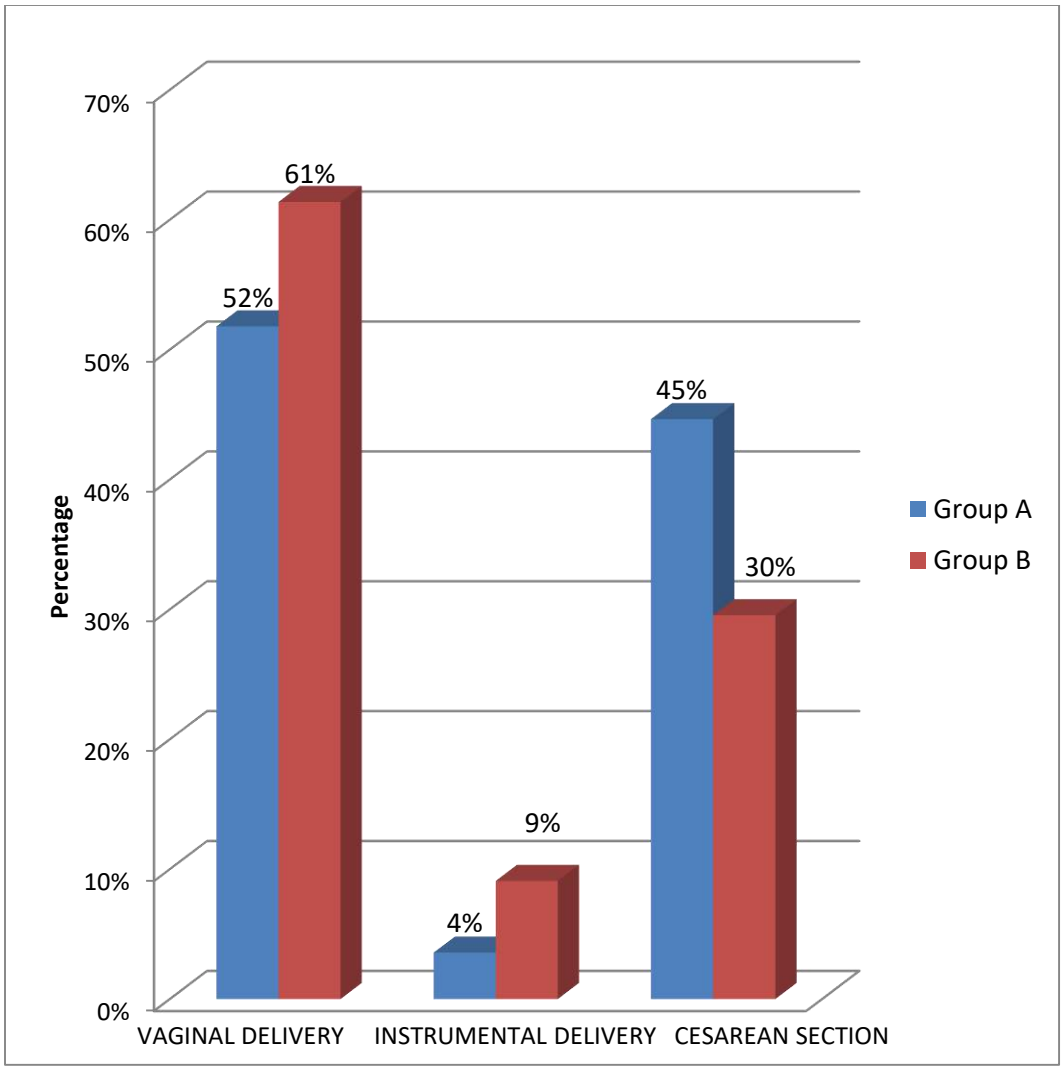


Figure 6: Distribution of patients according to the methods of induction of labour and the mode of delivery.

INDUCTION OF LABOUR

Induction of labour is characterized under the following parameters:

1. Indications for induction of labour
2. Modified bishops score and outcome of induction
3. Successful induction
4. Comparison of maternal and demographic parameters of successful induction
5. Need of oxytocin
6. Time interval between instillation of drug to onset of good uterine contractions
7. Time interval between instillation of drug to delivery
8. Adverse events
9. Number of per vaginal examinations
10. Patient satisfaction score

1. Indications for induction of labour.

Table 8: Distribution of patients on the basis of indications of induction of labour and inducing agents.

	Group A		Group B		Total	Chi- square value	p-value
INDICATION FOR INDUCTION OF LABOUR	n=56	(%)	n=44	(%)			
Postdatism	11	20%	4	9%	15	2.152	0.142
PROM >24 hours	5	9%	7	16%	12	1.137	0.286
Preeclampsia	10	18%	3	7%	13	2.655	0.103
Intrahepatic cholestasis of pregnancy	6	11%	9	20%	15	1.833	0.176
Gestational diabetes	7	13%	4	9%	11	0.293	0.589
Fetal growth restriction	3	5%	4	9%	7	0.528	0.468
Decreased fetal movements	6	11%	9	20%	15	1.833	0.176
Others	7	13%	4	9%	11	0.293	0.589

In group A, 20% (n=11) patients were induced for postdatism, 9% (n=5) patients were induced for pre labour rupture of membranes, 11% (n=6) patients were induced for intrahepatic cholestasis of pregnancy, 13% (n=7) patients were induced for gestational diabetes, 5% (n=3) patients were induced for fetal growth restriction , 11% (n=6) patients were induced on decreased fetal movements, and 13% (n=7) patients were induced for other indications.

In group B, 9% (n=4) patients were induced for post datism, 16% (n=7) patients were induced for pre labour rupture of membranes, 20% (n=9) patients were induced for intrahepatic cholestasis of pregnancy, 9% (n=4) patients were induced for gestational diabetes, 9% (n=4) patients were induced for fetal growth restriction , 20% (n=9) patients were induced on decreased fetal movements, and 9% (n=4) patients were induced for other indications. There was no statistically significant difference between the two groups. The most common indication was post datism in group A and fetal growth restriction and decreased fetal movements in group B.

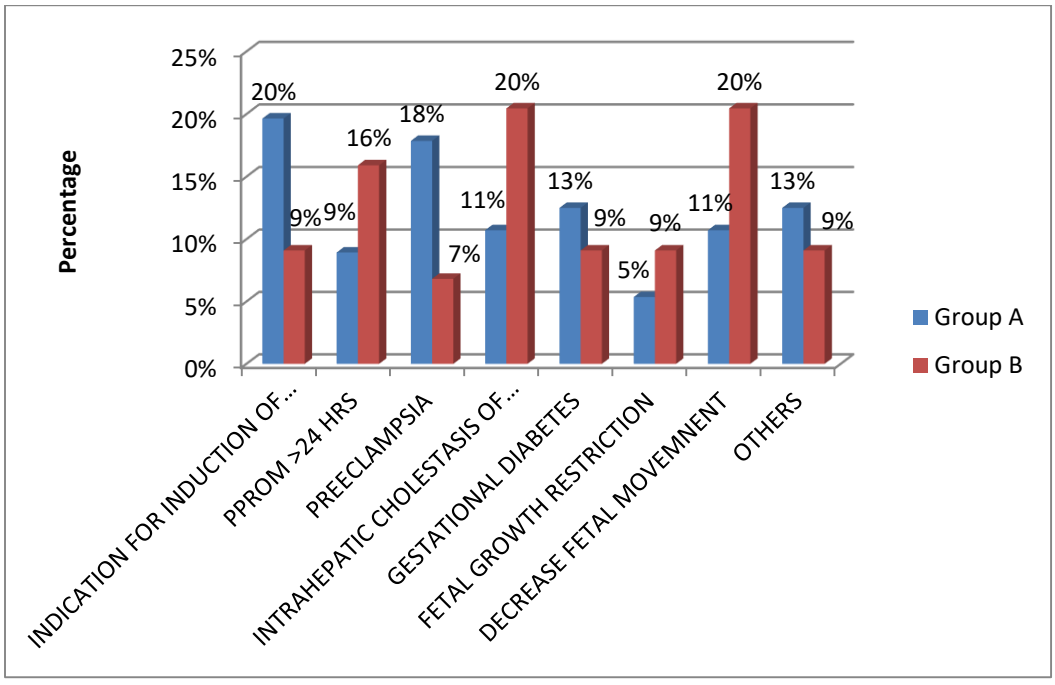


Figure 7: Distribution of patients between indications of induction of labour and inducing agent.

2. Modified bishops score and outcome of induction
    i. Patients in group A were assessed for modified bishops score
        A. At the start of induction

Table 9: Distribution of patients in group A according to modified bishops score (MBS) at start of induction.

Group A (n=56)		AT START OF INDUCTION	
MBS	2	2	4%
	3	21	38%
	4	22	39%
	5	11	20%
Total		56	100%

In group A, at the start of induction, 4% (n=2) patients had MBS 2, 38% (n=21) patients had MBS 3; 39 % (n=22) patients had an MBS of 4; 20% (n=11) patients had an MBS of 5. None of the patients had an MBS of 6 or more. Hence, all patients in this group (n=56) were administered intravaginal pessary.

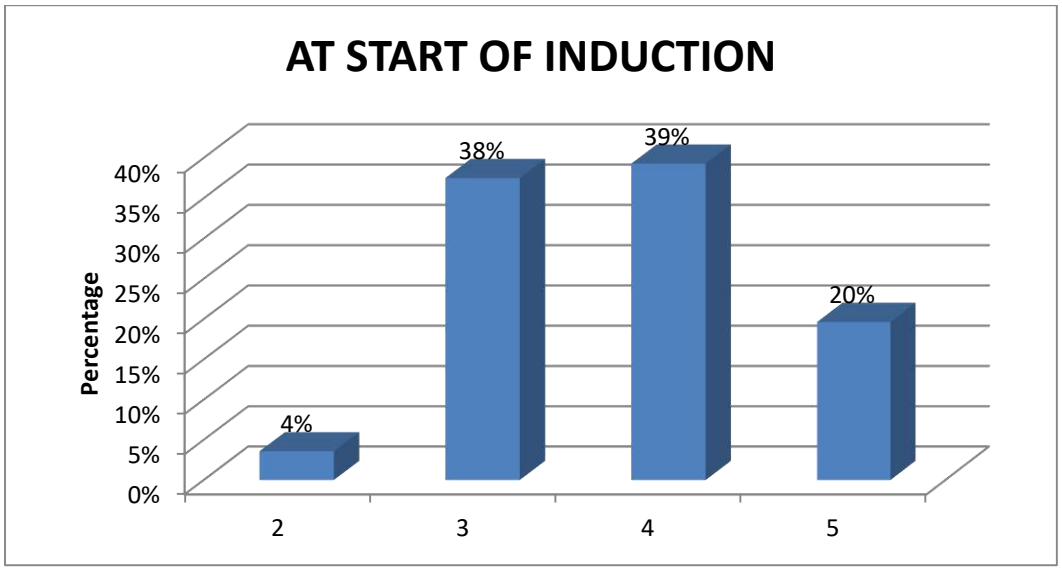


Figure 8: Distribution of patients in group A according to modified bishops score (MBS) at start of induction.

B. After 24 hours from start of induction.

Table 10: Distribution of patients in group A according to modified bishops score (MBS) and outcome after 24 hours of induction.

Group A (n=56)		AFTER 24 HRS	
MBS	2	0	0%
	3	0	0%
	4	4	7%
	5	4	7%
	≥ 6	38	68%

After 24 hours, none of the patients in group A had an MBS of 3 or less; 7% (n=4) had an MBS of 4; 7% (n=4) patients had an MBS of 5; 68% (n=38) patients had an MBS of 6 or more. This indicates that patients with MBS 6 or more 68% (n=38). Out of the remaining patients 7% (n=4) patients underwent vaginal and 11% (n=6) patients had a caesarean section. None of the patients underwent an instrumental delivery.

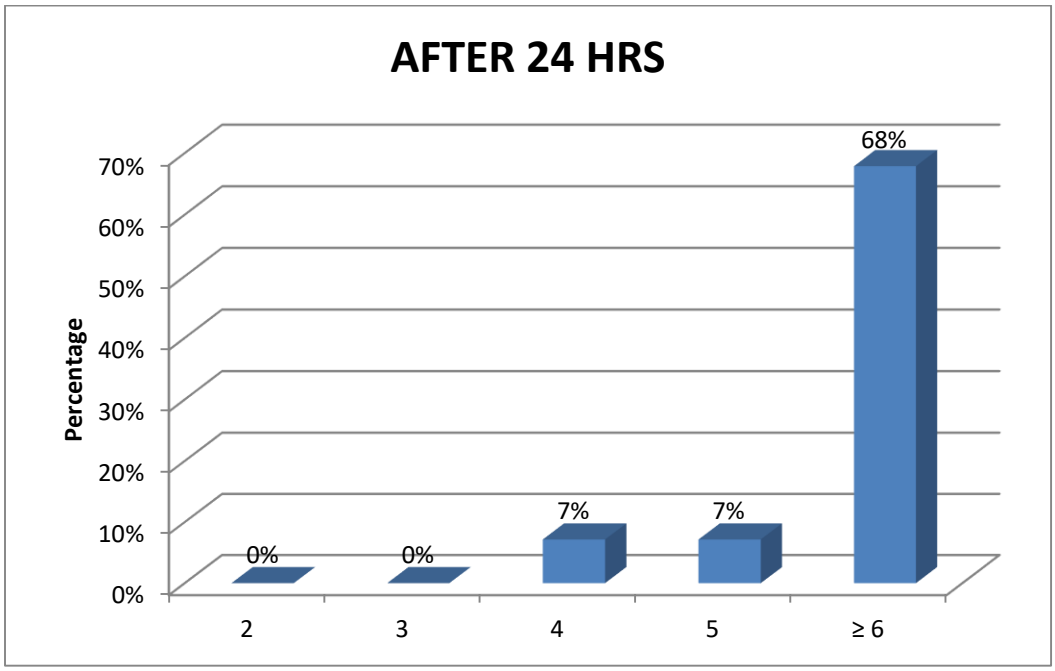


Figure 9: Distribution of patients in group A according to modified bishop's score at start of after 24 hours from start of induction.

ii. Patients in group B were assessed according to modified bishops score and outcome

A. At start of induction

Table 11: Distribution of patients in Group B according to modified bishop's score at start of induction.

MBS	Group B (n=44)	%
2	4	9%
3	11	25%
4	20	45%
5	9	20%
Total	44	100%

At the start of induction, all patients (n=44), had an MBS of less than 6. They were given the first dose of intracervical gel.

B. After six hours from start of induction.

Table 12: Distribution of patients in Group B according to modified bishops score after 6 hours from start of induction.

MBS AFTER 6 HOURS	No. (n=44)	%
2	3	7%
3	11	25%
4	21	48%
5	8	18%
6	1	2%
Total	44	100%

Patients were assessed after 6 hours from start of induction, 7% (n=3) had an MBS of 2, 25% (n=11) had an MBS of 3, 48% (n=21) had an MBS of 4, 18% (n=8) had an MBS of 5. One patient had an MBS equal to or more than 6. This patient was excluded from next dose of the gel. A total of 43 patients were analyzed after 12 hours for outcome.

C. After twelve hours from start of induction.

Table 13: Distribution of patients in Group B according to modified bishop's score and outcome after 12 hours from start of induction.

	GROUP B	
After 12 hours	n=43	%
3	4	9%
4	7	16%
5	11	25%
6	9	20%
Total	43	98%

43 patients were assessed after 12 hours from the start of induction. They were given a second dose of the gel. It was found that, out of the patients that received the second dose, 9% (n=3) had an MBS of 3, 16% (n=7) had an MBS of 4, 25% (n=11) had an MBS of 5, and 20% (n=9) had an MBS of 6 or more. Out of the remaining patients, 9% (n=4) patients underwent a caesarean section and 18% (n=8) patients underwent vaginal delivery. A total of 11 patients were excluded from the next dose. A total of 22 patients were analyzed after 18 hours for outcome.

D. After eighteen hours from start of induction

Table 14: Distribution of patients in Group B according to modified bishop's score and outcome after 18 hours from start of induction.

After eighteen hours	GROUP B	
MBS	n=22	%
4	2	9%
5	8	36%
6	3	14%
Total	22	100%

A total of 22 patients were evaluated after 18 hours from start of induction and were given third dose of intra cervical gel. Out of these, 9% (n=2) patients had an MBS of 4, 36% (n=8) patients had an MBS of 5, and 14% (n=3) patients had an MBS of 6 or more. Out of the remaining patients, 9% (n=2) patients underwent instrumental vaginal delivery; 27% (n=9) patients underwent non instrumental vaginal delivery and 5% (n=1) patients underwent a caesarean section.

3. Successful Induction

Table 15: Comparison of successful induction of labour between group A and group B.

		Group A		Group B		Total (n=100)	Chi-square value	p-value
		n=56.	%	n=44	%			
Successful Induction	Yes	42	75%	29	66%	71	0.989	0.320
	No	14	25%	15	34%	29		
Total		56	100%	44	100%	100		

The two groups of patients were compared based on the success of induction of labour. Induction was said to be successful if modified bishops score is more than or equal to 6. In Group A, 75% (n=42) patients had successful induction of labour, and 25% (n=14) did not have a successful induction.

In Group B, 66% (n=29) patients had successful induction and 34% (n=15) patients did not have successful induction. A total of 71 patients had successful induction the p value is 0.320 which is not statistically significant.

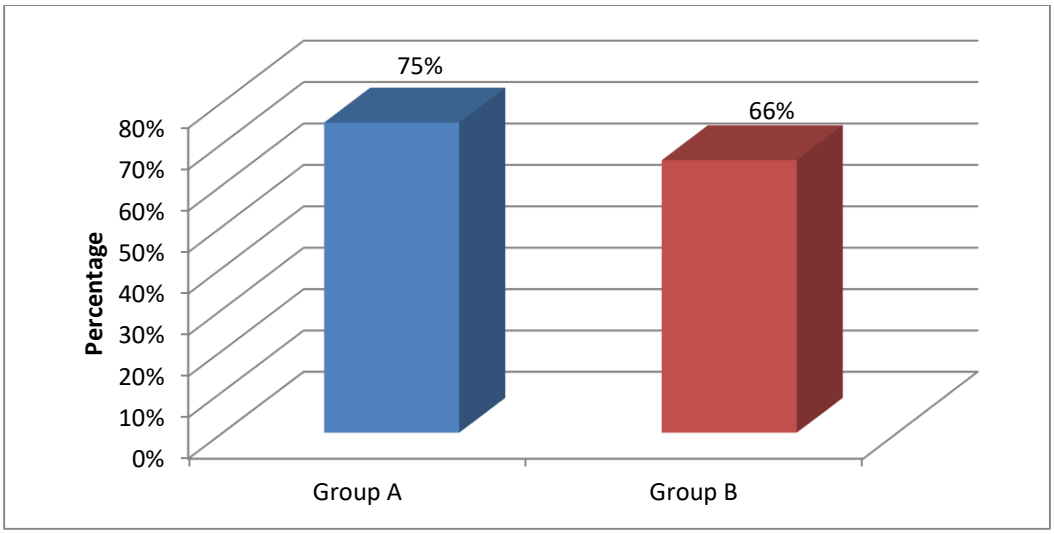


Figure 10: Comparison of successful induction of labour between two groups.

The patients with successful induction (n=71) were further divided into 2 groups; group C and group D.

Forty two patients in group A and 29 patients in group B who had successful induction formed group C and group D respectively.

4. Comparison of patients maternal demographic parameters of successful induction
   i. Distribution of patients with successful induction with age

Table 16: Distribution of patients according to age in group C and group D.

		Group C (n=42)		Group D (n=29)		Total	Chi-square value	p-value
	Age (in years)	n	%	n.	%			
Age	21-25	10	24%	3	10%	13	4.206	0.240
	26-30	23	55%	18	62%	41		
	31-35	7	17%	8	28%	15		
	35-40	2	5%	0	0%	2		

Among the patients who underwent successful induction, in the age group of 21-25 years 24% (n=10) patients versus 10% (n=3) patients ; in ages of 26 to 30 years 55% (n=23) versus 62% (n=18) patients; in ages of 31 to 35 years 17% (n=7) patients versus 28% (n=8) patients; in ages 36 to 40 years 5% (n=2) patients versus none patients belonged to groups C and D respectively. The maternal age of induction was not statistically significant in both the groups. (p value was 0.240)

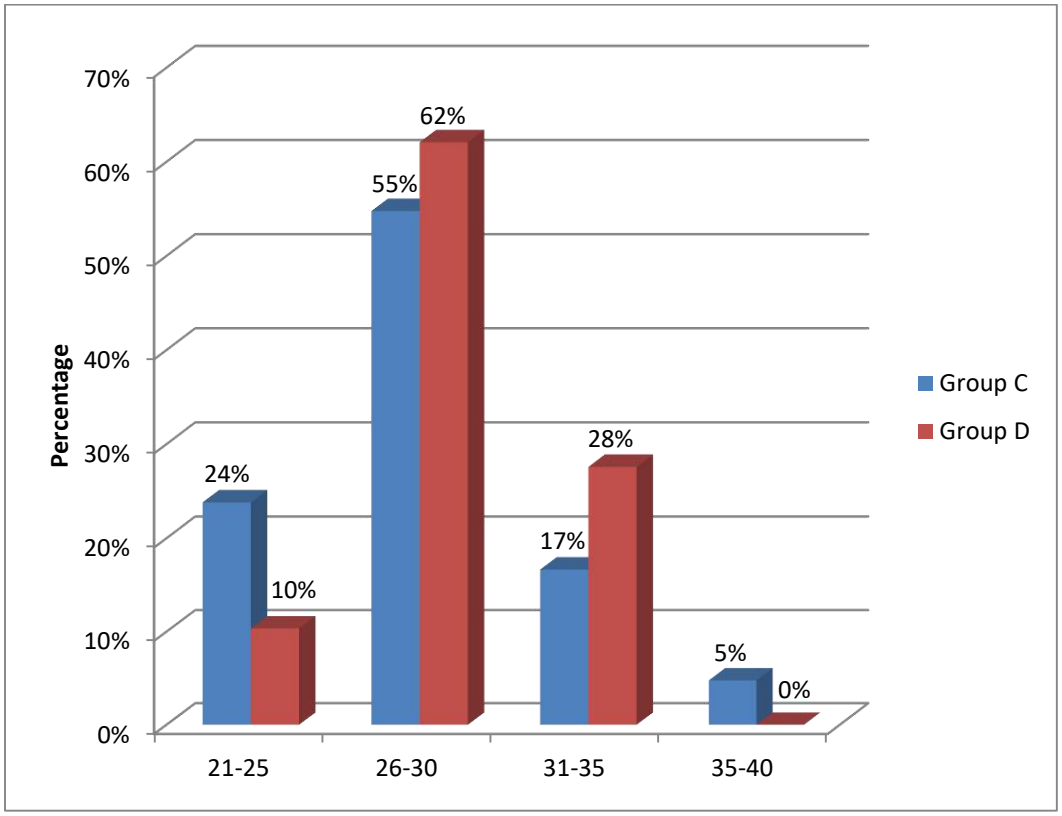


Figure 11: Distribution of patients according to age in group C and group D.

ii. Distribution of patients with succcesful induction of labour according to their socioeconomic class

Table 17: Distribution of according to their socioeconomic class in groups C and group D.

		Group C (n= 42)		Group D (n=29)		Total	Chi-square value	p-value
Socio-Economic Status	**Class**	n	%	n.	%			
	Lower	13	31%	7	24%	20	0.480	0.787
	Middle	12	29%	10	34%	22		
	Upper	17	40%	12	41%	29		

Among the patients that had a successful induction, In group C, 13 (31%) patients belonged to lower socioeconomic class, 12 (29%) patients belonged to middle socio-economic class while 17 (40%) patients belonged to upper socio-economic class.

In group D, 7 (24%) patients belonged to lower socio-economic class, 10 (34%) patients belonged to middle socio-economic class and 12 (41%) patients belonged to upper socioeconomic class . The socioeconomic status was not statistically significant in both the groups (p value was 0.787).

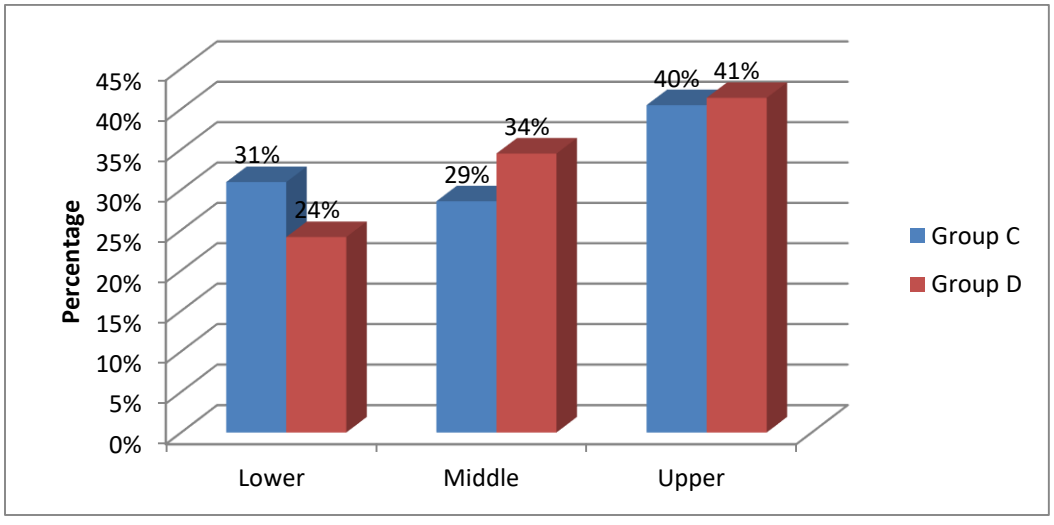


Figure 12: Distribution of patients according to their socioeconomic class in group C and group D.

iii. Distribution of patients with successful induction according to period of gestation

Table 18: Distribution of patients according to period of gestation in group C and group D.

		Group C (n=42)		Group D (n=29)		Total	Chi-square value	p-value
Period of gestation	**Gestational age**	n	%	n.	%			
	37-37+^{6}	14	33%	12	41%	26	1.186	0.756
	38-38+^{6}	14	33%	9	31%	23		
	39-39+^{6}	8	19%	6	21%	14		
	> 40	6	14%	2	7%	8		

In patients with successful induction, in group C , 33% (n=14) were induced at 37-37+^{6} weeks, 33% (n=14) patients were induced at 38-38+^{6} weeks, 19% (n=8) were induced at 39 to 39+^{6} weeks and 14% (n=6) were induced at gestational age of equal to or more than 40 weeks.

In group D , 41% (n=12) were induced at 37-37+^{6} weeks, 31% (n=9) were induced at 38-38+^{6} weeks, 21% (n=6) were induced at 39-39+^{6} weeks and 7% (n=2) patients were induced at a gestational age of more than 40 years. There was no statistically significant difference between the groups. (p value was 0.756). The most common gestation at which induction was done was 37-37+^{6} weeks and 38-38+^{6} for group C and 37-37+^{6} for group D .

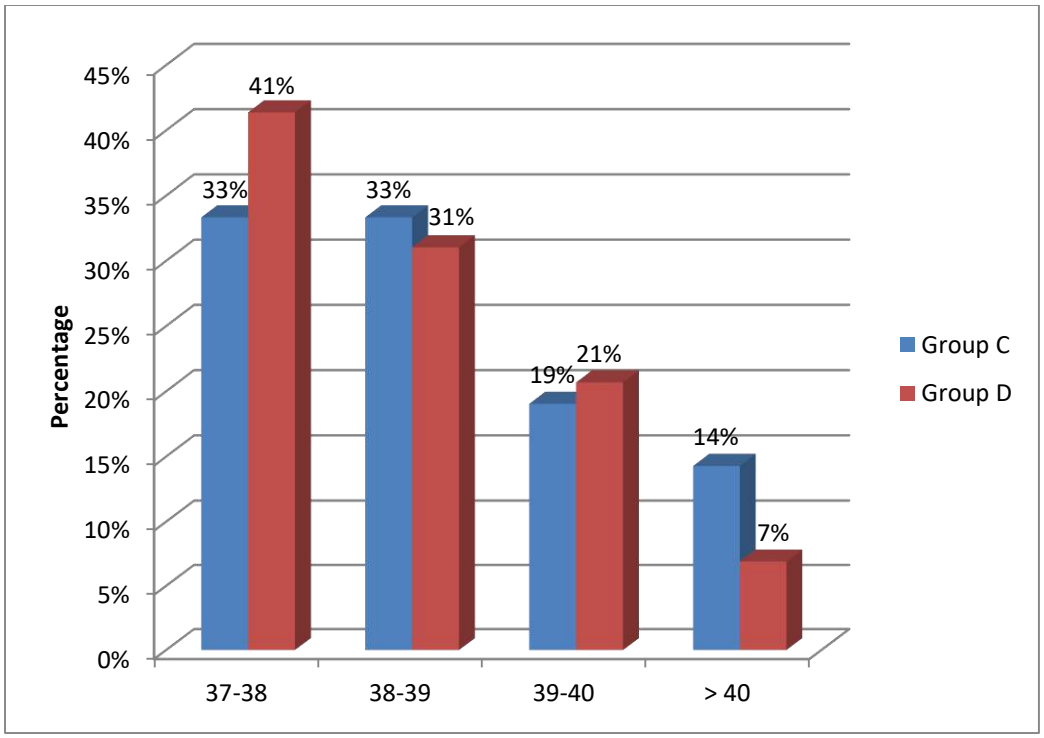


Figure 13: Distribution of patients according to period of gestation in group C and group D.

iv. Distribution of patients with successful induction according to gravidity

Table 19: Distribution of patients according to gravidity in group C and group D.

		Group C		Group D		Total	Chi-square value	p-value
		n.	(%)	n	(%)			
Gravidity	Multigravida	8	28%	21	72%	29	20.220	0.001
	Primigravida	34	81%	8	19%	42		

In group C, 81% (n=34) women with successful induction were primigravida as compared to 19% (n=8) women in group D. 28 % (n=8) women in group C were multigravida as compared to 72% (21) women in group D. The p value was 0.001 which was statistically significant.

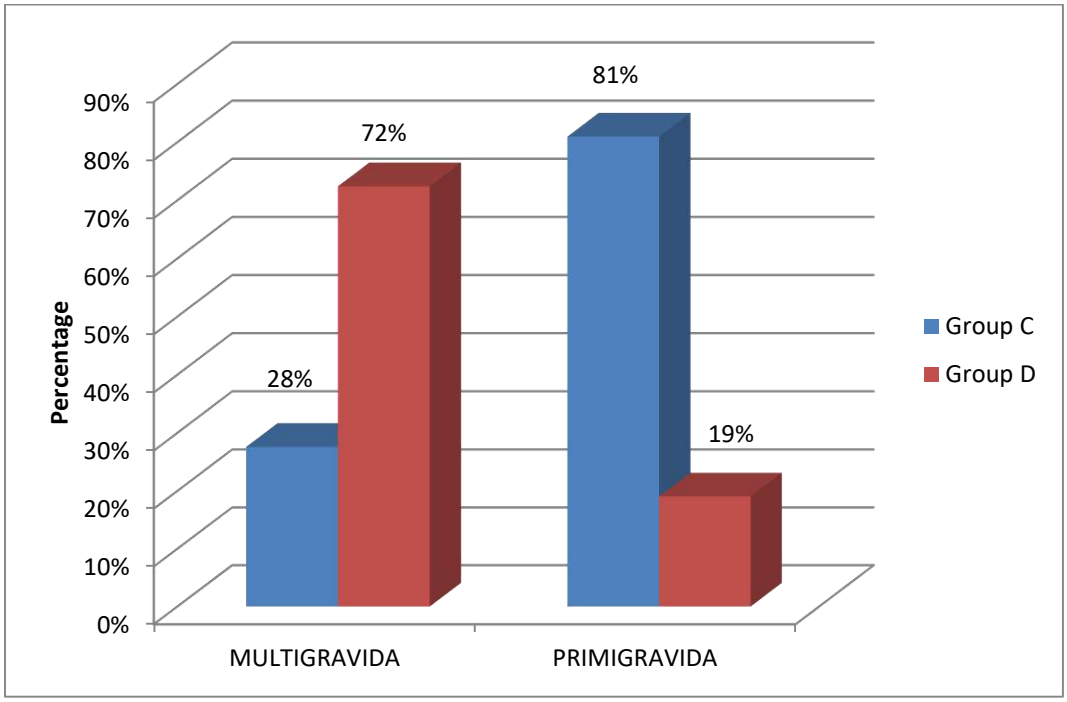


Figure 14: Distribution of patients according to gravidity in group C and group D.

v. Distribution of patients with successful induction according to mode of delivery

Table 20: Distribution of patients according to mode of delivery in group C and group D.

	Group C (n=42)		Group D (n=29)		Total	Chi-square value	p-value
Mode of delivery	n	%	n.	%			
Vaginal delivery	29	69%	24	83%	53	1.704	0.192
Instrumental delivery	2	5%	3	10%	5	0.817	0.366
Cesarean section	11	26%	2	7%	13	4.269	0.060

In patients that had successful induction, 69% (n=29) patients in group C underwent vaginal delivery 26% (n=11) patients underwent cesarean section, and 5% (n=2) patients underwent instrumental delivery. In group D, 83% (n=24) patients underwent vaginal delivery, 10% (n=3) patients underwent instrumental delivery and 7% (n=2) patients underwent cesarean section (MBS > 6). A majority had vaginal delivery in both the groups. The p value (more than 0.005) in these groups was not statistically significant.

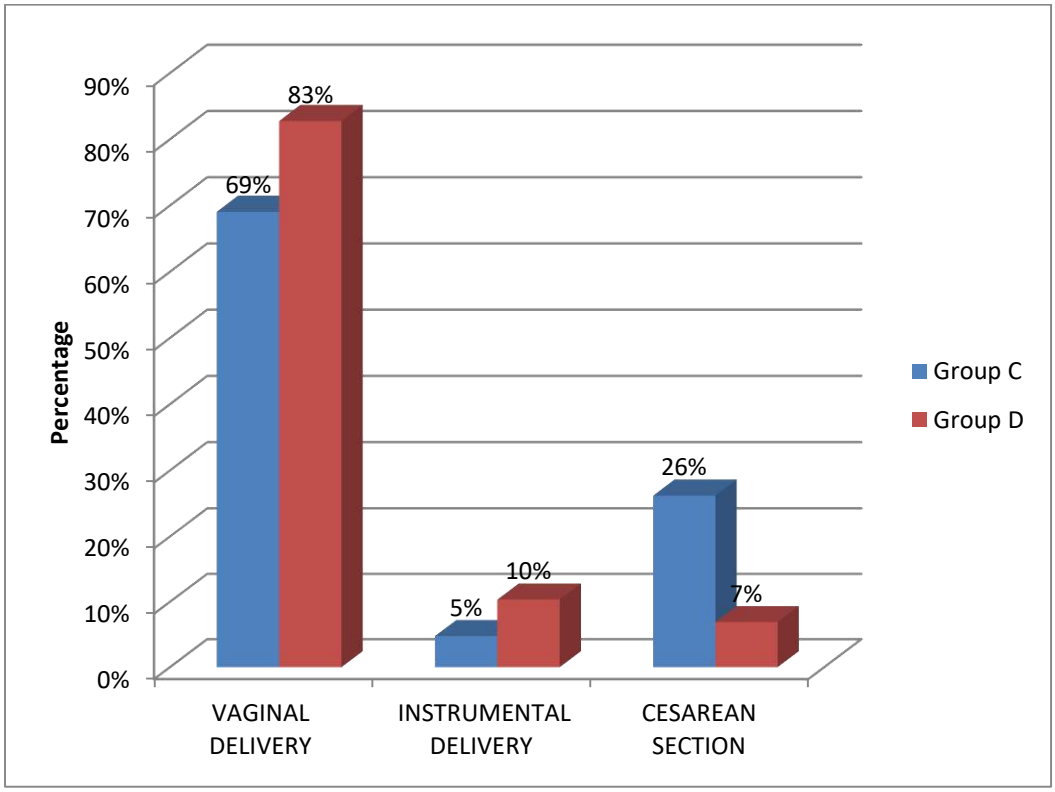


Figure 15: Distribution of patients according to mode of delivery in group C and group D.

5. Need of oxytocin

A. Comparison for need of oxytocin between the group A and group B

Table 21: Comparison for need of oxytocin between the group A and group B.

		Group A		Group B		Total	Chi-square value	p-value
		n=56	(%)	n=44	(%)			
Need of oxytocin	Yes	20	36%	13	30%	33	0.424	0.515
	No	36	64%	31	70%	67		
Total		56	100%	44	100%	100		

In group A, 36% (n=20) patients required oxytocin, whereas 64% (n=36) patients did not require it. In Group B, 30% (n=13) patients required oxytocin, and 70% (n=31) patients did not require oxytocin. The p value was 0.515 suggesting that there was no statistically significant difference between the two groups. A majority did not require augmentation with oxytocin in both the groups.

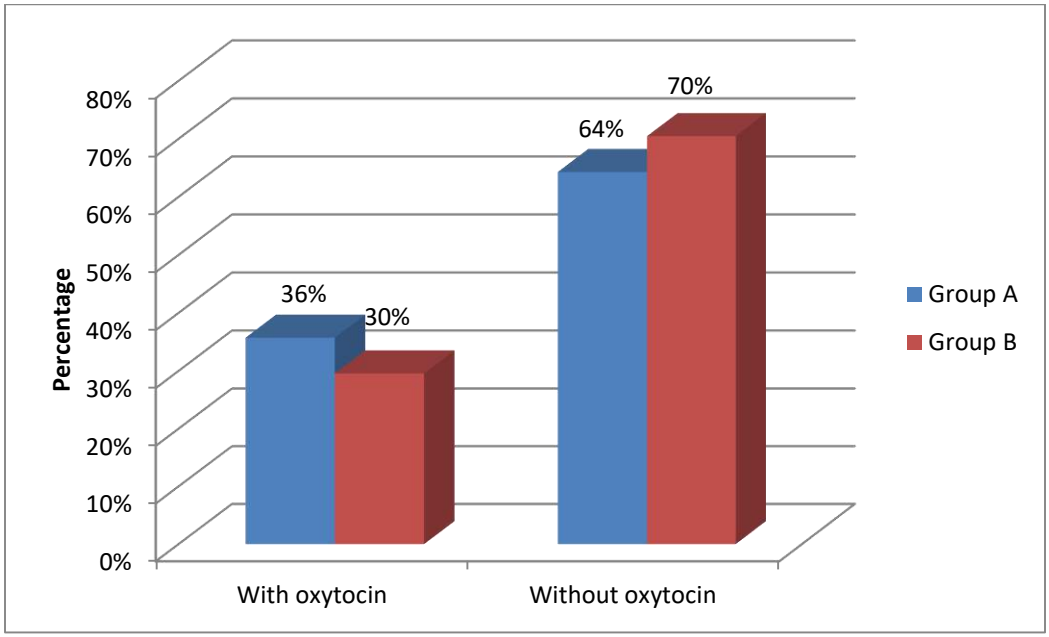


Figure 16: Comparison for need of oxytocin in group A and Group B.

B. Comparison for need of oxytocin between groups C and D.

Table 22: Comparison for need of oxytocin between groups C and D.

		Group C		Group D		Total	Chi-square value	p-value
		n=42	%	n=29	%			
Need of oxytocin	yes	20	48%	10	34%	30	1.213	0.271
	no	22	52%	19	66%	41		

In group C, 48% (n=20) patients required oxytocin, whereas in group D, 34% (n=10) patients required oxytocin. 52% (n=22) patients in group C and 66% (n=19) patients in group D did not require it the p value was 0.515 suggesting that there was no statistically significant difference between the two groups.

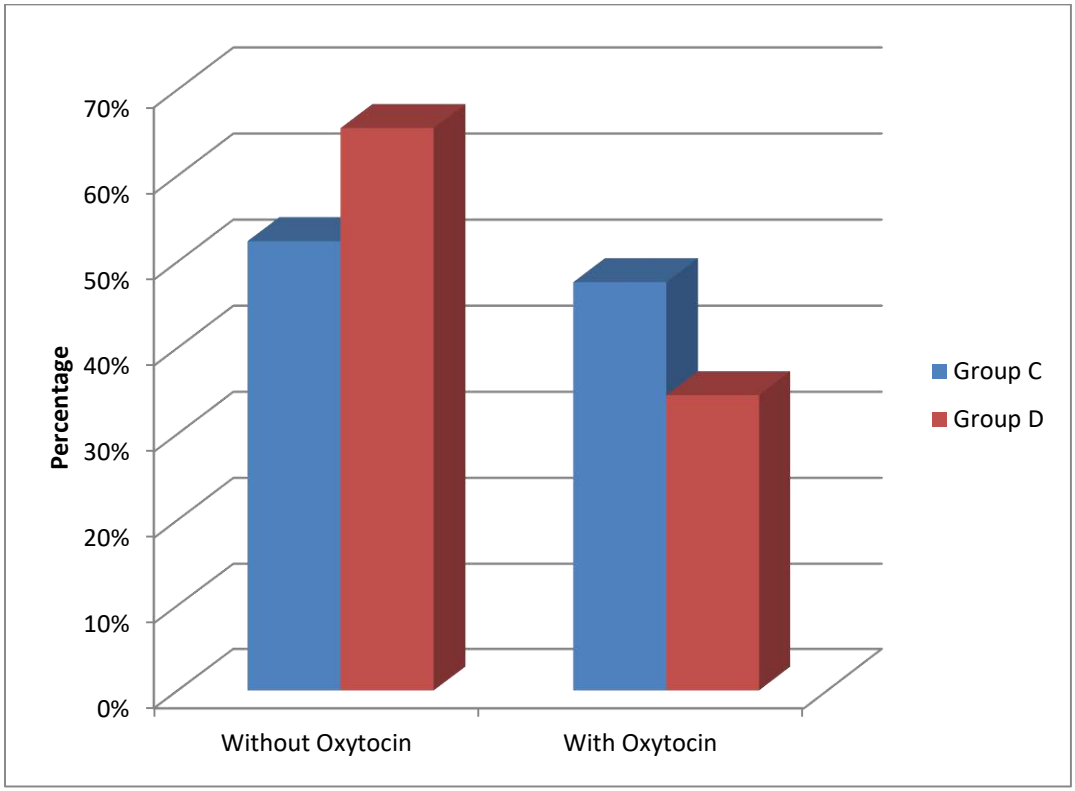


Figure 17: Comparison for need of oxytocin between groups C and D.

6. Time interval between instillation of drug to onset of good uterine contractions

Table 23: Comparison between the mean time taken from instillation of drug to onset of good uterine contractions in group A and group B.

Time interval between instillation of drug and onset of good contractions (in hours)	Group A (n=56)		Group B (n=44)		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
	12.07	4.95	12.28	6.46	0.164	0.870	-2.33	2.75

In Group A, the average time taken from instillation of drug to onset of good uterine contractions (five contractions or less in 10 min averaged over a 30 min window) was 12.07 hours and in Group B, the average time taken from induction of labour to onset of good uterine contractions was 12.28 hours. The p value was 0.870 suggesting no statistical significance between the groups.

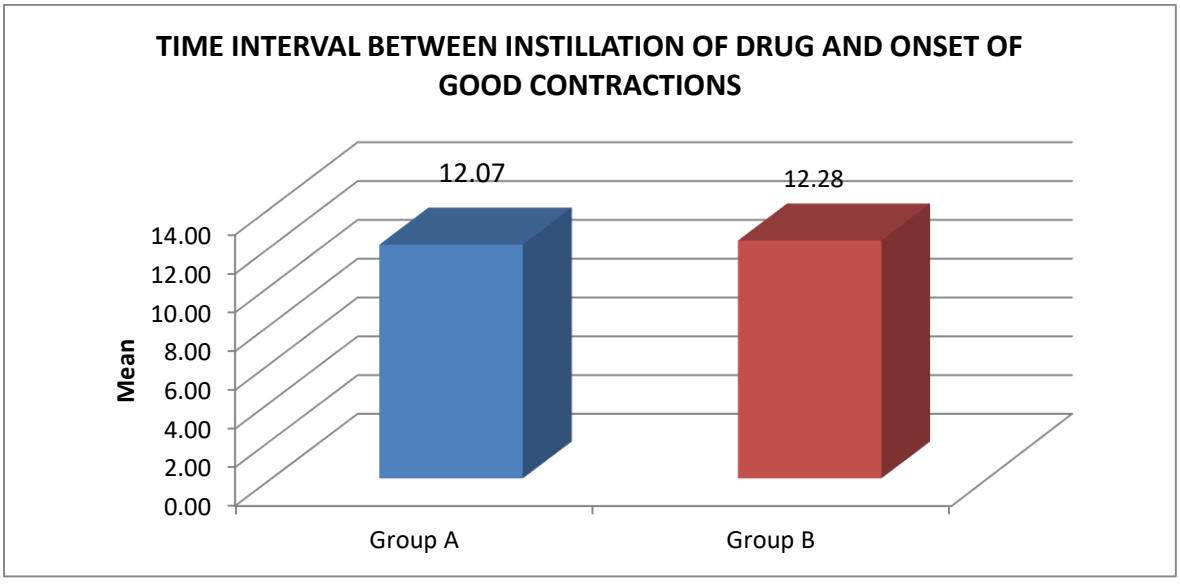


Figure 18: Comparison between the mean time taken from instillation of drug to onset of good uterine contractions in group A and group B.

7. Time taken between instillation of drug to delivery

Table 24: Comparison of average time taken between instillation of drug and time of delivery between group A and Group B.

Time interval between instillation of drug and time of delivery (in hours)	Group A n=56		Group B n= 44		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
	17.87	6.38	16.16	7.33	-1.249	0.215	-4.44	1.01

In Group A, the average time interval between instillation of drug and delivery was 17.87 hours and in Group B, the average time taken between instillation of drug and delivery was 16.16 hours. The p value was 0.215, there was no statistically significant difference between the two groups.

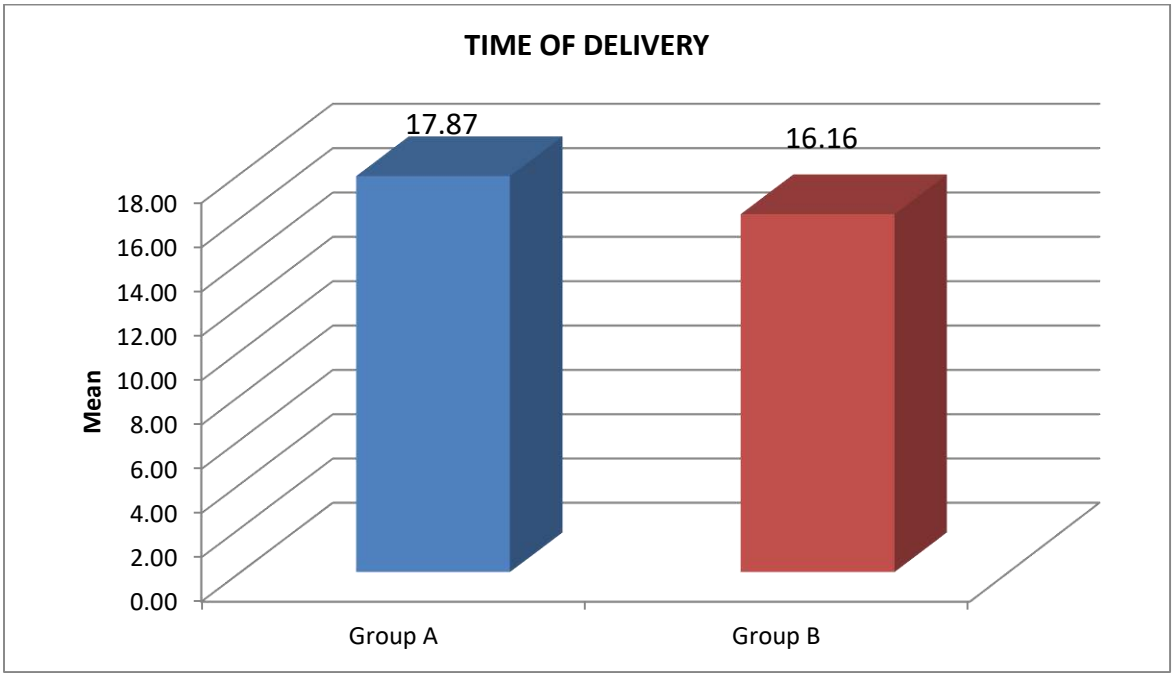


Figure 19: Comparison of average time taken between instillation of drug and time of delivery between group A and Group B.

8. Adverse events
    A. Comparison of adverse events in group A and group B

Table 25: Comparison of adverse events in group A and group B.

	Group A		Group B		Total	Chi-square value	p-value
Adverse events	n=56	(%)	n=44	(%)			
Uterine hyper stimulation	0	0%	0	0%	0	0.000	1.000
Fetal distress	4	7%	4	9%	8	0.127	0.722
Meconium stained liquor	7	13%	1	2%	8	3.502	0.061
Fetal distress plus meconium stained liquor	3	5%	1	2%	4	0.610	0.435
Uterine rupture	0	0%	0	0%	0	0.000	1.000
Retained placenta	1	2%	1	2%	2	0.000	1.000
Postpartum hemorrhage	4	7%	8	18%	12	0.630	0.427

*none of the patients reported spontaneous expulsion of pessary in group A

In either of the groups, none of the patients had uterine hyper stimulation. In Group A, 7% (n=4) patients had fetal distress, 13% (n=7) patients had meconium stained liquor, 5% (n=3) patients had fetal distress and, no patient had uterine rupture, 2% (n=1) patients had retained placenta and 7% (n=4) patients had postpartum hemorrhage.

In group B, 9% (n=4) patients had fetal distress, 2% (n=1) patients had meconium stained liquor, 2% (n=1) patients had fetal distress and meconium stained liquor, no patient had uterine rupture or uterine hyper stimulation, 2% (n=1) patients had retained placenta and 18% (n=8) patients had postpartum hemorrhage. The p value was more than 0.005

indicating no statistical significance between groups. Majority patients had MSL in group A and PPH in group B.

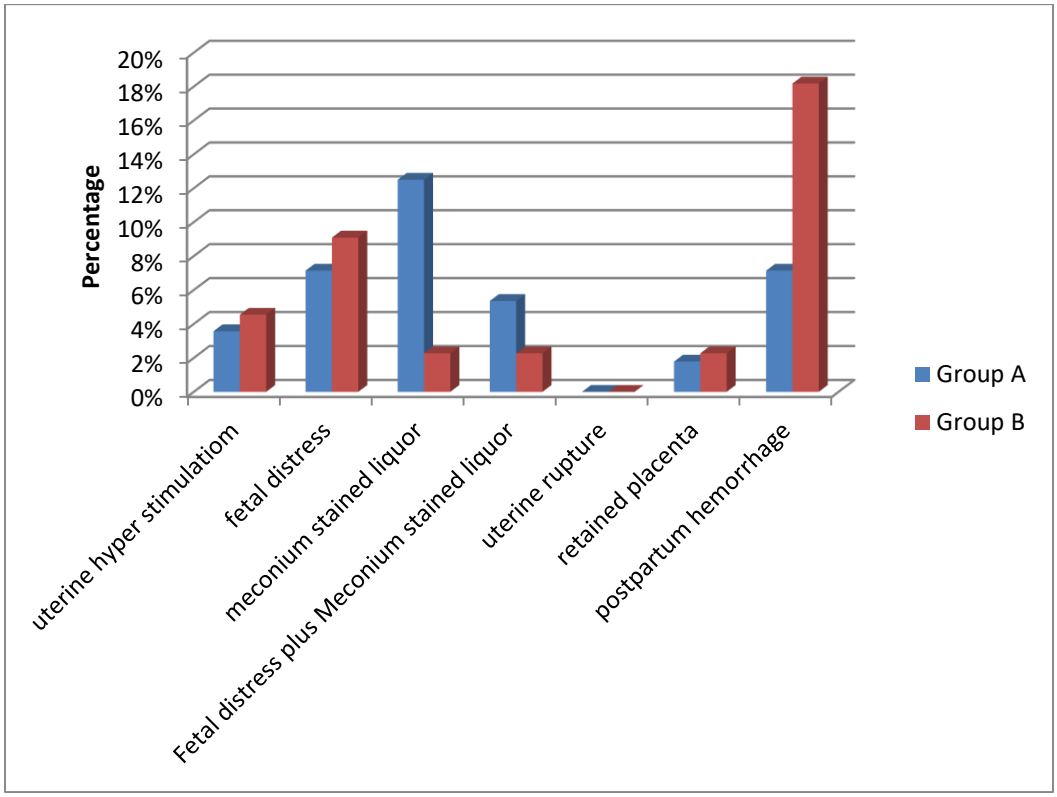


Figure 20: Comparison of adverse events in group A and group B.

B. Comparison of adverse events between the two group C and group D

Table 26: Comparison of adverse events between the two group C and group D.

	Group C		Group D		Total	Chi-square value	p-value
Adverse events	n=42	%	n=29	Group B			
Uterine hyper stimulation	0	0%	0	0%	0	0.000	1.000
Fetal distress	3	7%	0	0%	3	2.163	0.141
Meconium stained liquor	3	7%	0	0%	3	2.163	0.141
Fetal distress plus meconium stained liquor	2	5%	1	3%	3	0.073	0.787
Postpartum hemorrhage	2	5%	1	3%	3	0.073	0.787
Retained placenta	1	2%	0	0%	1	0.700	0.403

*none of the patients reported spontaneous expulsion of pessary in group C

In patients with successful induction, none of the patients had uterine hyper stimulation in either of the groups. Fetal distress was seen in 7% (n=3) versus none; meconium stained liquor in 7% (n=3) versus none; fetal distress with meconium stained liquor in 5% (n=2) versus 3% (n=1) patients; postpartum hemorrhage in 5% (n=2) versus 3% (n=1) patients and retained placenta in 2% (n=1) versus none patients in groups C and D respectively. The p value of all groups was more than 0.005 which was not statistically significant.

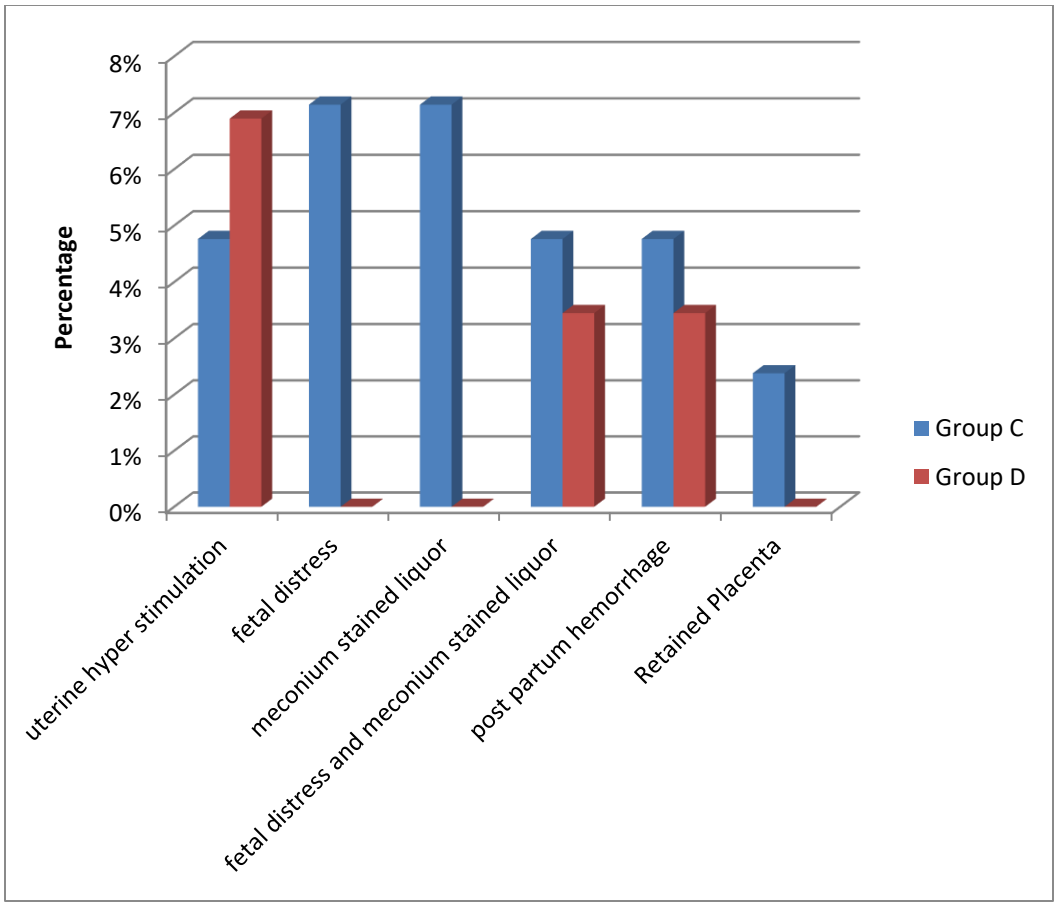


Figure 21: Comparison of adverse events between the two group C and group.

9. Number of per vaginal examinations

   i. Number of per vaginal examinations between group A and group B

Table 27: Average number of per vaginal examinations between group A and group B.

	Group A		Group B		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
Number Of Pv Examination	5.27	2.52	8.89	2.98	-6.575	0.000	-4.711	-2.526

In group A, the average number of per vaginal examinations was 5.57 as compared to group B in which the number of per vaginal were 8.89. The p value was 0.000 indicating a statistically significant difference between the two groups.

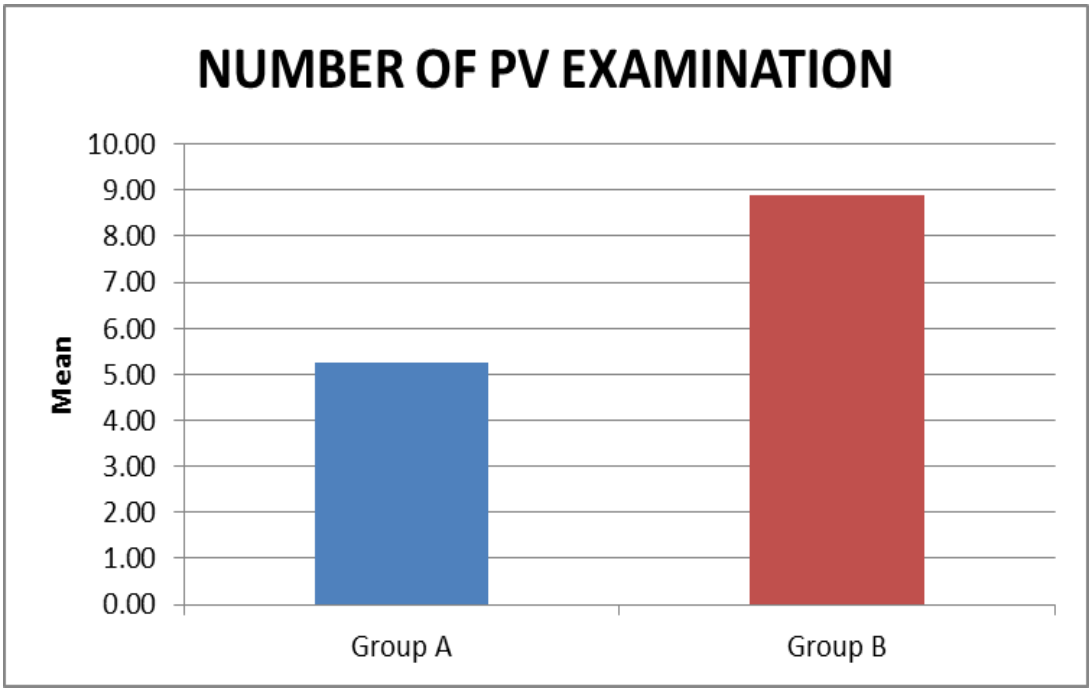


Figure 22: Average number of per vaginal examinations between group A and group B.

ii. Number of per vaginal examinations between group C and group D

Table 28: Average number of per vaginal examinations between group C and group D.

	Group C (n=42)		Group D (n=29)		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
Number Of Pv Examination	6.02	2.37	8.14	2.36	-3.700	0.000	-3.254	-0.974

In group C, the average number of per vaginal examinations was 6.02 as compared to group D in which the number of per vaginal were 8.14. The p value was 0.000 indicating a statistically significant difference between the two groups.

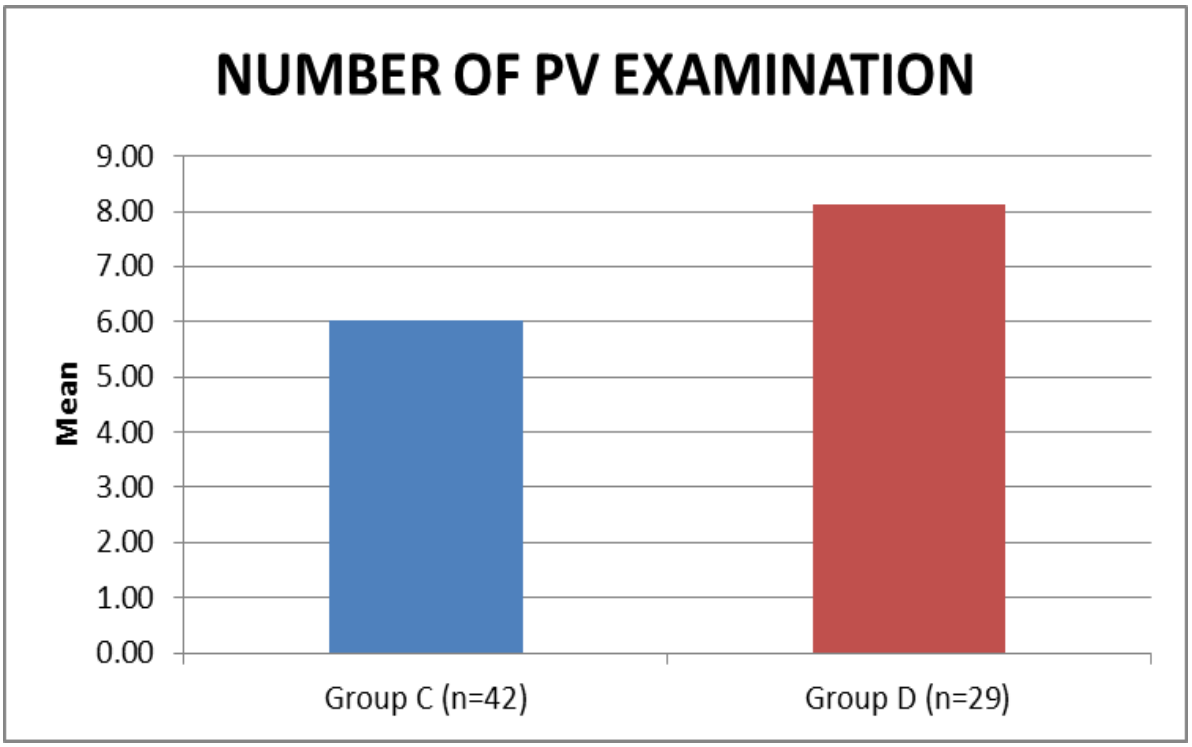


Figure 23: Average number of per vaginal examinations between group C and group D.

10. Patient satisfaction score

A. Distribution of patient according to patient satisfaction in group A and group B

Table 29: Distribution of patient according to patient satisfaction in group A and group B.

	Group A		Group B		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
Patient Satisfaction	8.14	1.05	7.25	0.94	4.407	0.000	0.491	1.295

The patients were asked to rate the level of patient satisfaction on a scale of 0 to 10. With 0 being the level of least satisfaction and 10 being the level of highest satisfaction. This was a subjective assessment. In group A, the mean satisfaction was 8.14 as compared to group B where it was 7.25. The p value was 0.000 which was statistically significant.

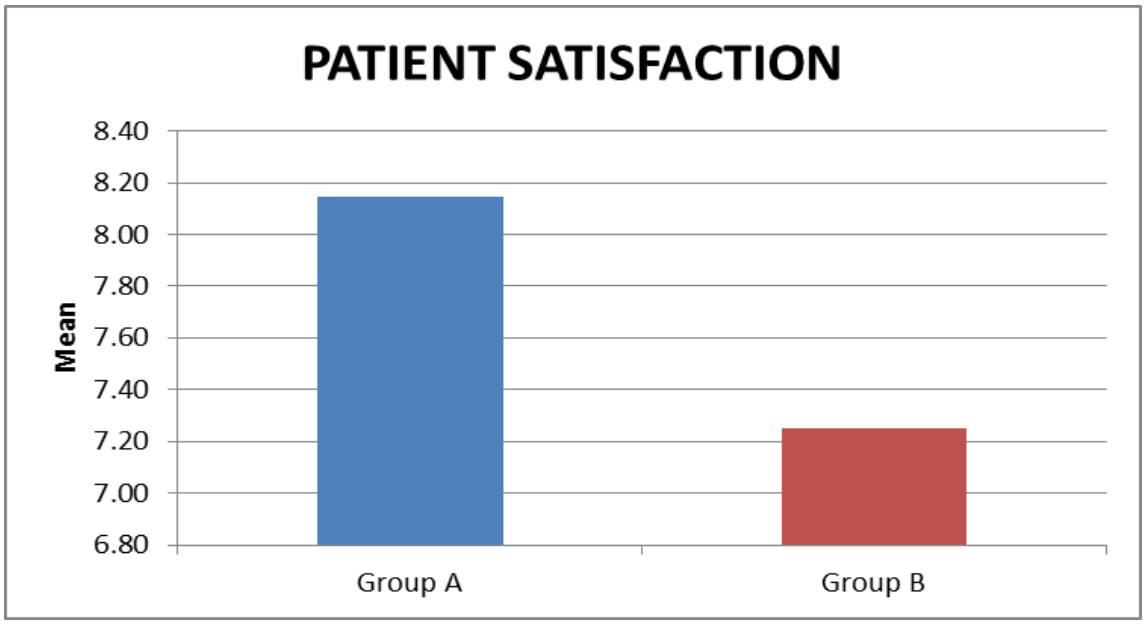


Figure 24: Distribution of patient according to patient satisfaction in group A and group B.

B. Distribution of patient according to patient satisfaction in group C and group D

Table 30: Distribution of patient according to patient satisfaction in group C and group D.

	Group C (n=42)		Group D (n=29)		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
Patient Satisfaction	8.07	1.11	7.28	0.96	3.128	0.003	0.288	1.303

In group C, the mean satisfaction was 8.07 as compared to group D where it was 7.28. The p value was 0.003 which was statistically significant.

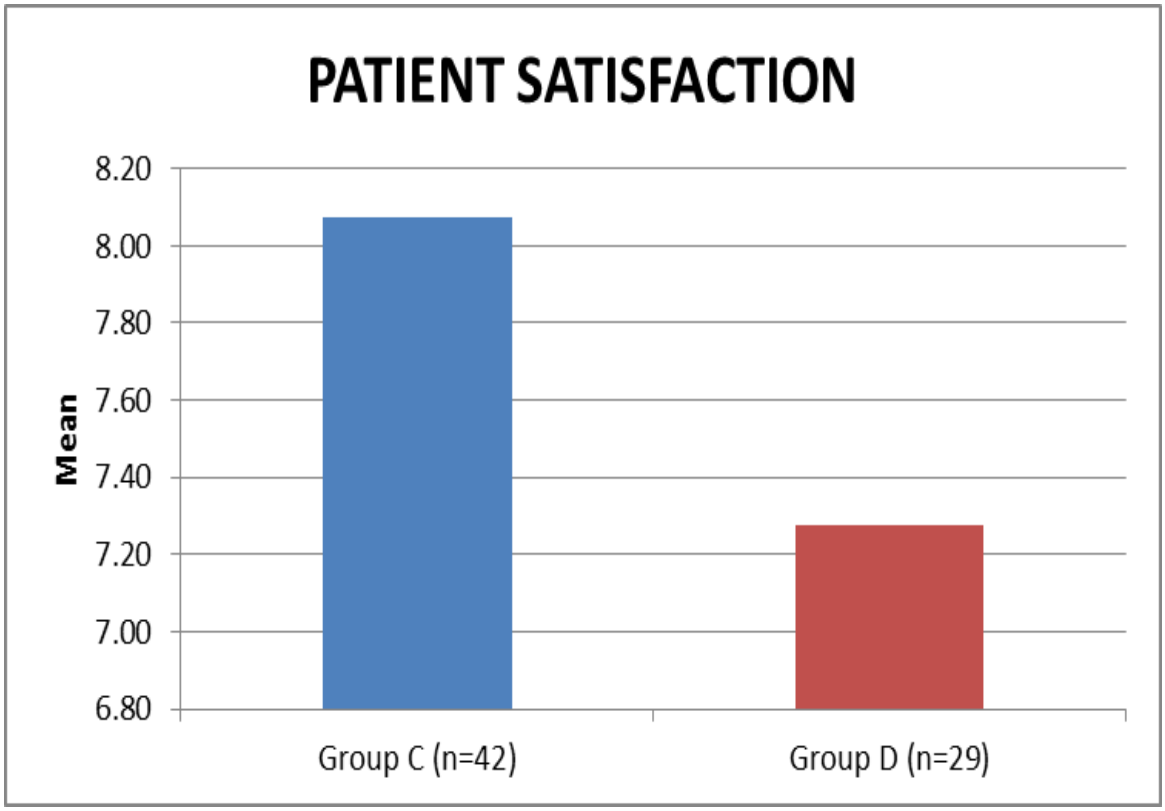


Figure 25: Distribution of patient according to patient satisfaction in group C and group D.

FETAL PARAMETERS

The fetal parameters under study are

1. Live birth
2. Fetal sex
3. Fetal birth weight
4. Agar Score
5. Admission to NICU
6. Indication of admission to NICU

1. Live birth

Table 31: Distribution of patients who gave live births in group A and group B.

		Group A		Group B		Total
		n=56	%	n=44	%	
Live Birth	YES	56	100%	44	100%	100
Total		56	100%	44	100%	100

In our study all patients in both the groups gave birth to live babies.

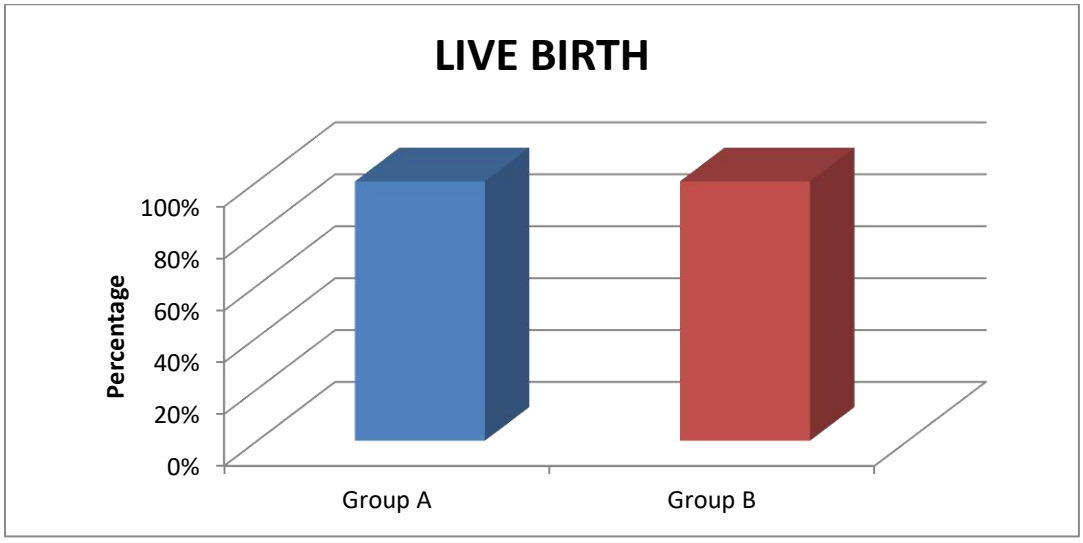


Figure 26: Distribution of patients who gave live births in group A and group B.

2. Fetal Sex

Table 32: Distribution of sex of the baby between group A and group B.

		Group A		Group B		Total	Chi-square value	p-value
		n=56	(%)	n=44	(%)			
Fetal Sex	Female	23	41%	15	34%	38	0.510	0.475
	Male	33	59%	29	66%	62		
Total		56	100%	44	100%	100		

Forty one percent (n=23) fetuses in Group A and 34% (n=15) fetuses in group B belonged to female sex.

Fifty nine percent (n=33) fetuses in group A and 66% (n=29) fetuses in group B belonged to male sex.

There no statistical significance between the two groups. (p value = 0.475)

A majority of patients delivered male babies in both the groups.

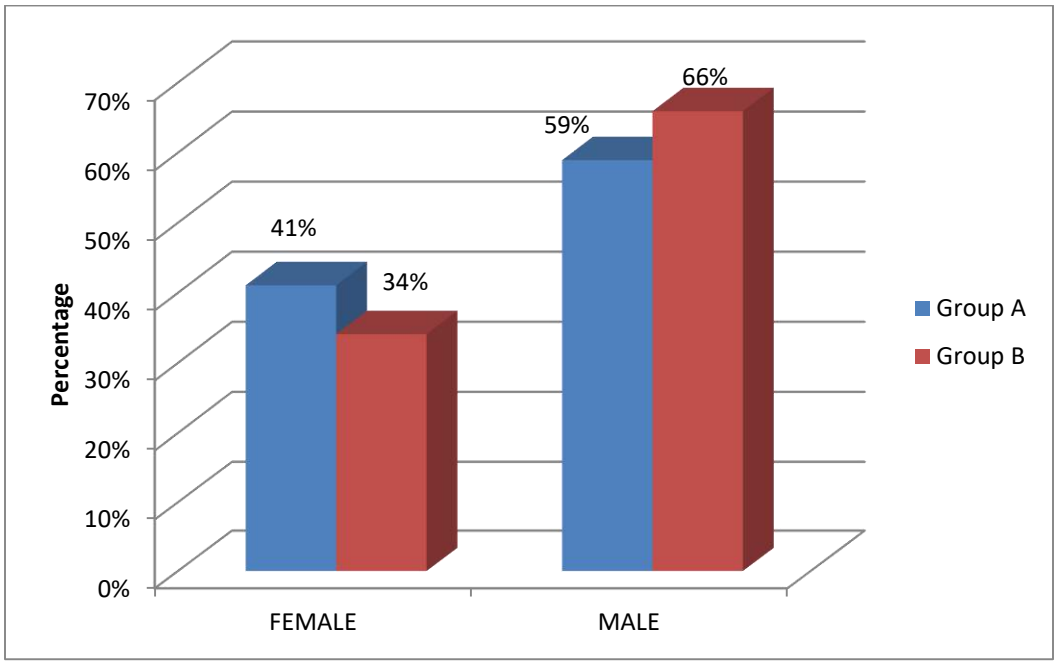


Figure 27: Distribution of sex of the baby between group A and group B.

3. Fetal birth weight

   i. Comparison between the mean fetal birth weight of between group A and group B

Table 33: Comparison between the mean fetal birth weight of between group A and group B.

	Group A (n=56)		Group B (n=44)		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
fetal weight (in grams)	3043.57	453.19	2943.86	459.86	-1.085	0.281	-282.06	82.64

The mean fetal birth weight in group A was 3043.57 grams and the mean birth weight in group B was 2943.86 grams. The p value was 0.281 indicating no statistical significance between the groups.

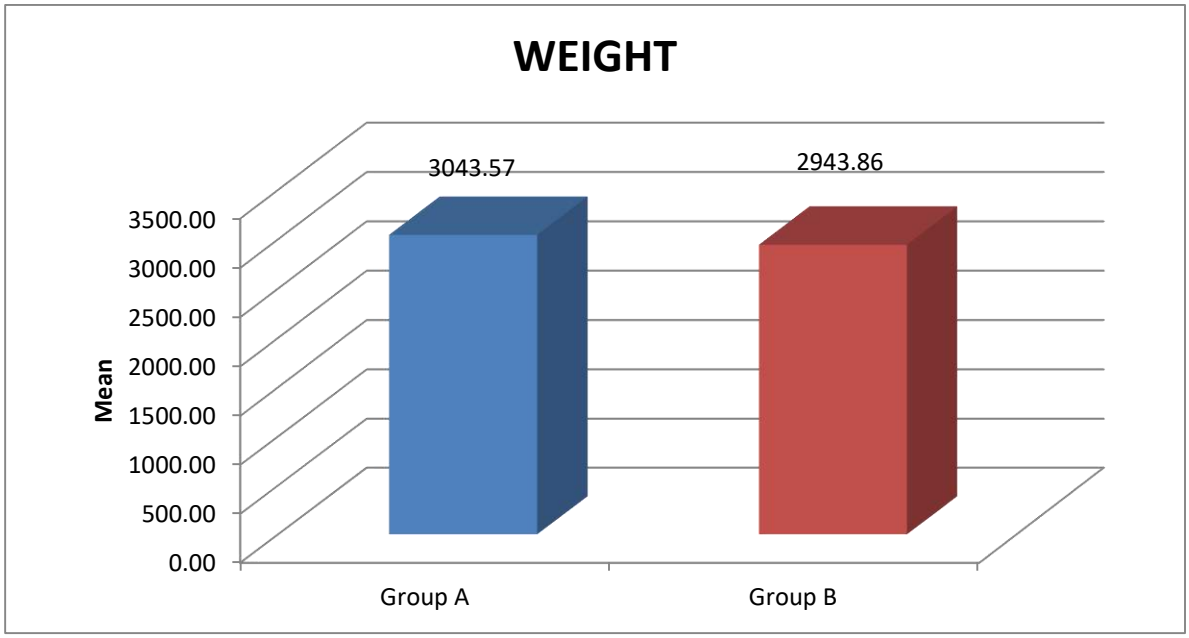


Figure 28: Comparison between the mean fetal birth weight groups A and group B.

ii. Comparison between the mean fetal birth weight of between group C and group D

Table 34: Comparison between the mean fetal birth weight of between group C and group D.

	Group C (n=42)		Group D (n=29)		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
Weight (In Grams)	3017.38	438.46	2856.90	435.60	1.520	0.133	-50.145	371.114

The mean fetal birth weight in group C and D was 3017.38 and 2856.90 grams respectively. The p value was 0.133 indicating no statistical significance between the groups.

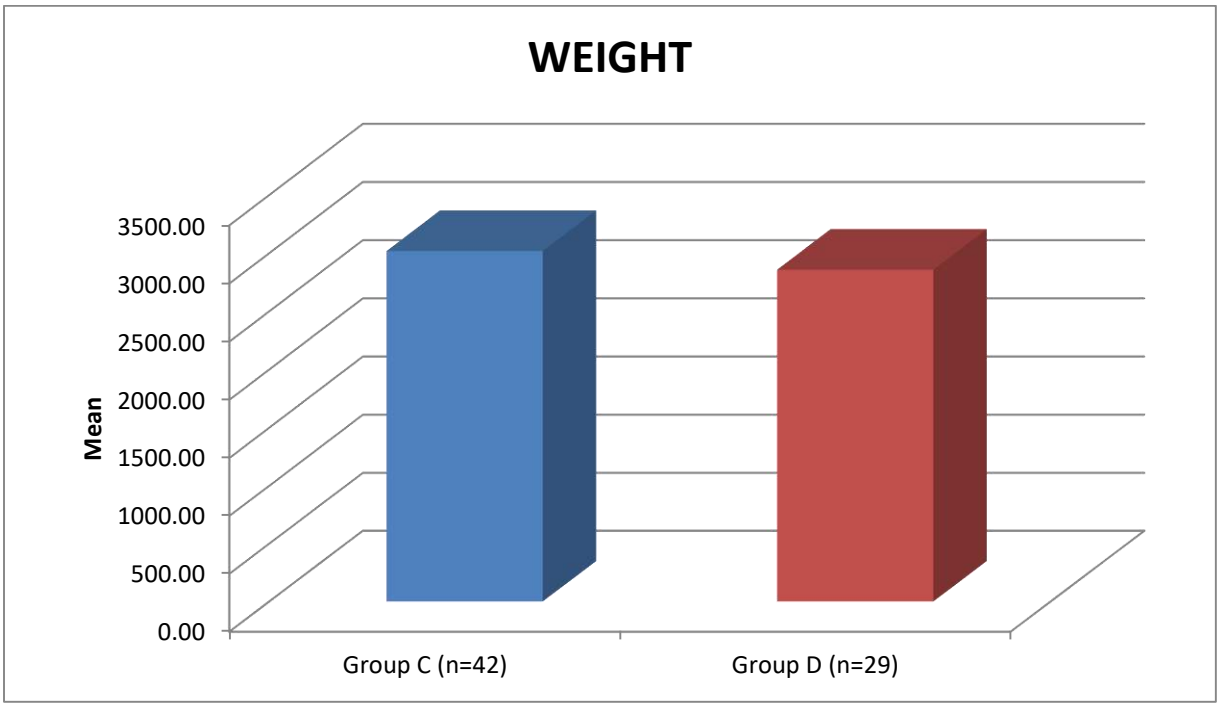


Figure 29: Comparison between the mean fetal birth weight groups C and group D.

4. Apgar score

   i. Distribution of babies born according to Apgar score at 1minute in group A and group B

Table 35: Distribution of babies born according to Apgar score at 1 minute in group A and group B.

		Group A		Group B		Total	Chi-square value	p-value
		n.	%	n.	%			
Apgar Score At 1 Minute	5	1	2%	0	0%	1	3.520	0.318
	6	3	5%	0	0%	3		
	7	5	9%	3	7%	8		
	8	47	84%	41	93%	88		
	9	0	0%	0	0%	0		

In group A, 2% (n=1) patients had an Apgar score of 5, 5% (n=3) patients had an Apgar score of 6, 9% (n=5) patients had an Apgar score of 7 and majority 84% (n=47) patients had an Apgar score of 8. In Group B, no patient had an Apgar score of 6 or less, 7% (n=3) patients had an Apgar score of 7 and majority 93% (n=41) patients had an Apgar score of 8. The p value was 0.318 indicating that there was no statistically significant difference between the two groups. Majority of the patients had an Apgar score of more than 8 at 1 minute in both the groups.

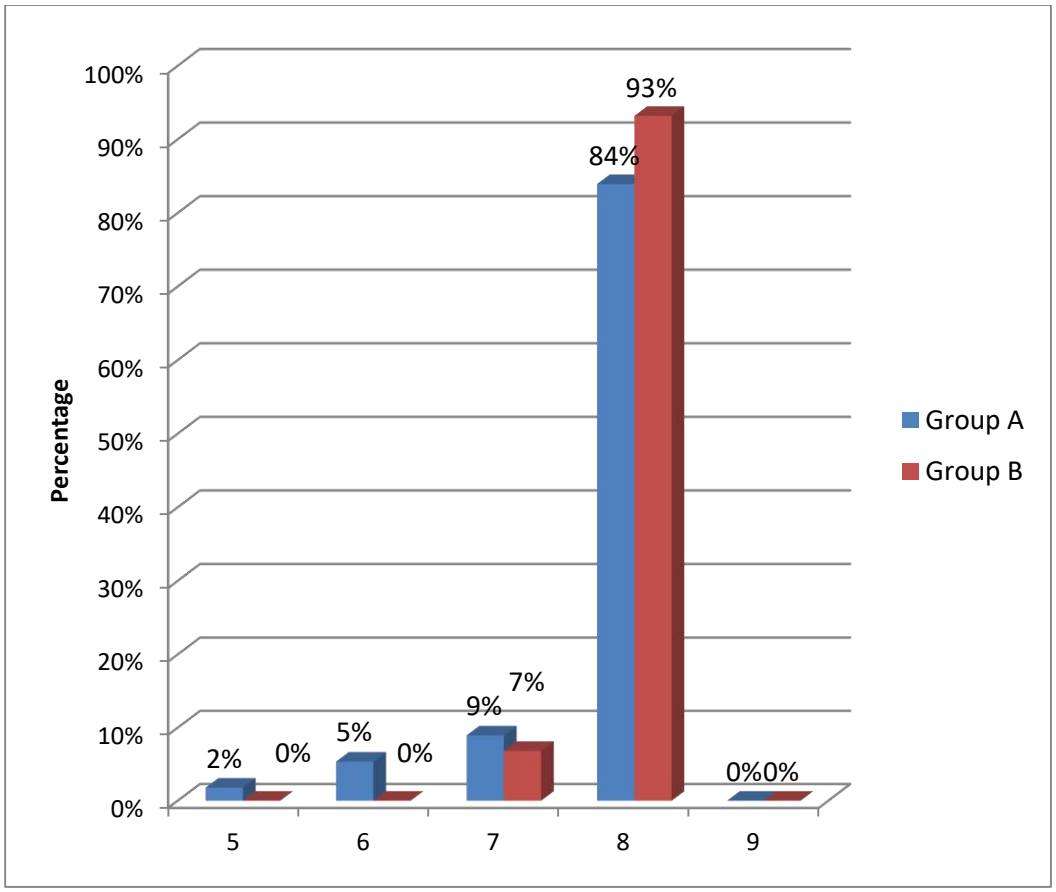


Figure 30: Distribution of babies born according to Apgar score at 1 minute in group A and Group B.

ii. Distribution of babies born according to Apgar score at 5 minutes in group A and group B

Table 36: Distribution of babies born according to Apgar score at 5 minutes in group A and group B.

		Group A		Group B		Total	Chi-square value	p-value
		n	%	n	%			
Apgar Score At 5 Minutes	5	0	0%	0	0%	0	0.004	0.950
	6	0	0%	0	0%	0		
	7	0	0%	0	0%	0		
	8	4	7%	3	7%	7		
	9	52	93%	41	93%	93		
Total		56	100%	44	100%	100		

In group A, 7% (n=4) patients had an Apgar score of 8 and 93% (n=52) patients had an Apgar score of 9. In group B, 7% (n=3) patients had an Apgar score of 8 and 93% (n=41) had an Apgar score of 9 at 5 minutes. The p value was 0.950 indicating that there was no statistically significant difference between the two groups. A majority patients had an Apgar score of 9 at 5 minutes in both the groups.

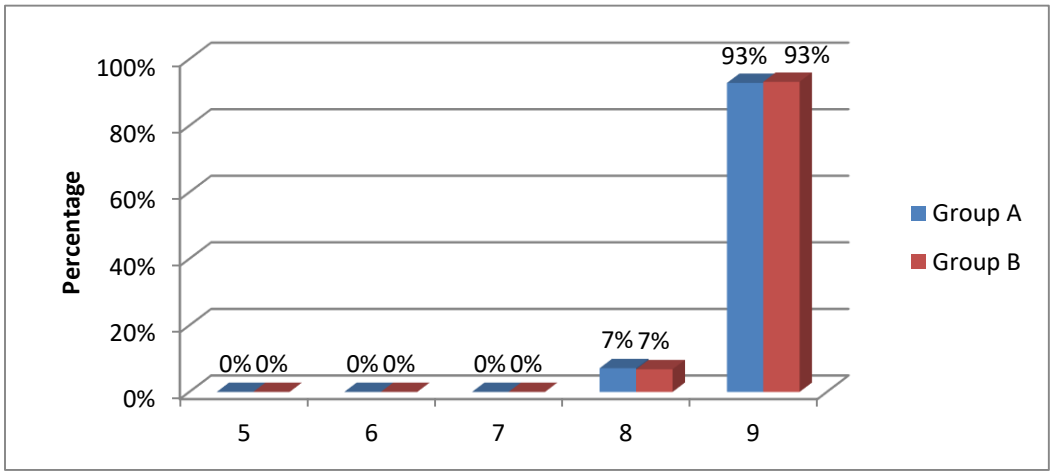


Figure 31: Distribution of babies born according to Apgar score at 5 minutes in group A and group B.

iii. Distribution of babies according to the mean Apgar score at 1 minute and 5 minute in group A and group B

Table 37: Distribution of babies according to the mean Apgar score at 1 minute and 5 minute in group A and group B.

	Group A n=56		Group B n=44		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
Apgar score at 1 minute	7.75	0.64	7.93	0.25	1.776	0.079	-0.02	0.38
Apgar score at 5 minutes	8.93	0.26	8.93	0.25	0.063	0.950	-0.10	0.11

In group A, the mean Apgar score at 1 minute was 7.75 +_ 0.64 and in group B the mean Apgar score at 1 minute was 7.93 +_0.25. It was not of statistical significance (p value=0.079).

The mean Apgar score at 5 minutes in group A was 8.93 +_0.26 and in Group B the mean Apgar score at 5 minutes was 8.93+_0.25. It was not of statistical significance (p value=0.950).

iv. Distribution of babies according to the Apgar score at 1 minute in both the group C and group D

Table 38: Distribution of babies according to the Apgar score at 1 minute in both the group C and group D.

		Group C		Group D		Total	Chi-square value	p-value
		n	%	N	%			
Apgar Score At 1 Minute	5	1	2%	0	0%	1	2.262	0.520
	6	2	5%	0	0%	2		
	7	5	12%	3	10%	8		
	8	34	81%	26	90%	60		
	9	0	0%	0	0%	0		

At 1 minute, in group C, 2% (n=1) patients had an Apgar core of 5, 5% (n=2) patients had an Apgar score of 6, 12% (n=5) patients had an Apgar score of 7 and majority 81% (n=34) patients had an Apgar score of 8. In Group D, no patient had an Apgar score of 6 or less, 10% (n=3) patients had an Apgar score of 7 and majority 90% (n=26) patients had an Apgar score of 8 at one minute. The p value was 0.520 indicating that there was no statistically significant difference between the two groups. A majority of the patients had an Apgar score of 8 at 1 minute in both the groups.

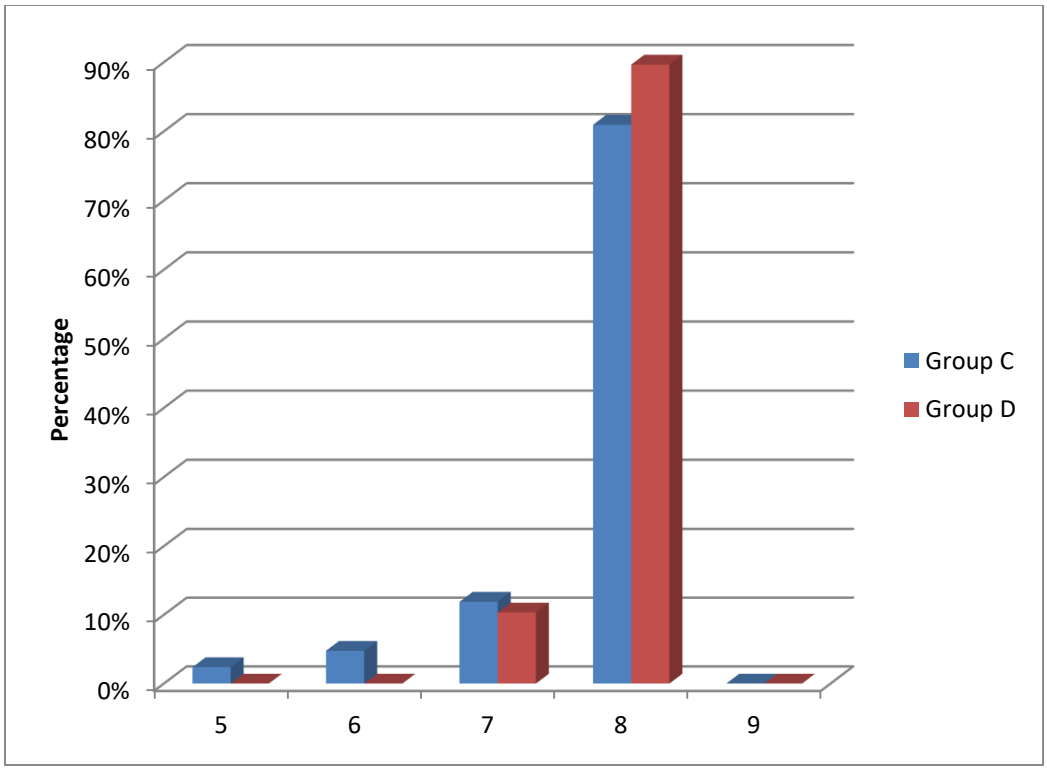


Figure 32: Distribution of babies according to the Apgar score at 1 minute in both the group C and group D.

v. Distribution of babies according to the Apgar score at 5 minutes in both the group C and group D

Table 39: Distribution of babies according to the Apgar score at 5 minutes in both the group C and group D.

		Group C		Group D		Total	Chi-square value	p-value
		n.	%	n.	%			
Apgar Score At 5 Minutes	5	0	0%	0	0%	0	0.013	0.909
	6	0	0%	0	0%	0		
	7	0	0%	0	0%	0		
	8	4	10%	3	10%	7		
	9	38	90%	26	90%	64		
Total		42	100%	29	100%	71		

At 5 minutes, in group C, 10% (n=4) patients had an Apgar score of 8, and 90% (n=38) had an Apgar score of 9. In Group D, 10% (n=3) patients had an Apgar score of 8 and 90% (n=26) had an Apgar score of 9 at 5 minutes. The p value was 0.909 indicating that there was no statistically significant difference between the two groups. A majority patients had an Apgar score of 9 at 5 minutes in both the groups.

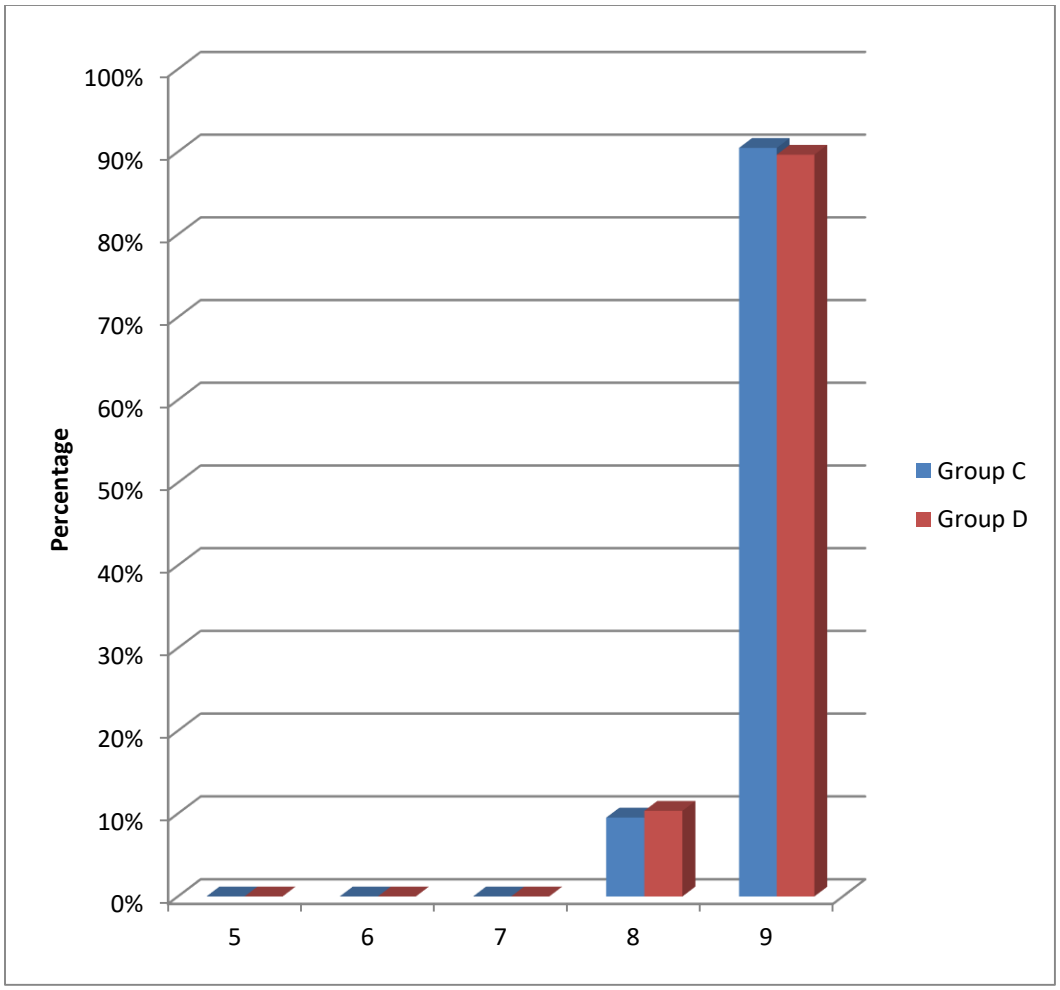


Figure 33: Distribution of babies according to the Apgar score at 5 minutes in both the group C and group D.

vi. Distribution of babies according to the mean Apgar score at 1 minute and 5 minute in group A and group B

Table 40: Distribution of babies according to the mean Apgar score at 1 minute and 5 minute in group A and group B.

	Group C (n=42)		Group D (n=29)		t	p-value	95% Confidence Interval of the Difference	
	Mean	SD	Mean	SD			Lower	Upper
Apgar score at 1 minute	7.71	0.67	7.90	0.31	-1.360	0.178	-0.450	0.085
Apgar score at 5 minutes	8.90	0.30	8.90	0.31	0.112	0.911	-0.137	0.154

In group C, the mean Apgar score at 1 minute was 7.71 +_ 0.67 and in group D the mean Apgar score at 1 minute was 7.90 +_0.31. It was not of statistical significance (p value=0.178).

The mean Apgar score at 5 minutes in group C was 8.90 +_0.30 and in Group D the mean Apgar score at 5 minutes was 8.90+_0.31. It was not of statistical significance (p value=0.911).

Admission to NICU

Table 41: Comparison of admission in NICU in group A and group B.

		Group A		Group B		Total	Chi-square value	p-value
		n=56	(%)	n=44	(%)			
Admission To NICU	YES	9	16%	2	5%	11	3.344	0.106
	NO	47	84%	42	95%	89		
Total		56	100%	44	100%	100		

16% (n=9) patients in group A required NICU admission.

5% (n=2) patients in groups B required NICU admission. The difference between the two groups was not statistically significant. (p value=0.106)

The majority of the patients did not require NICU admission.

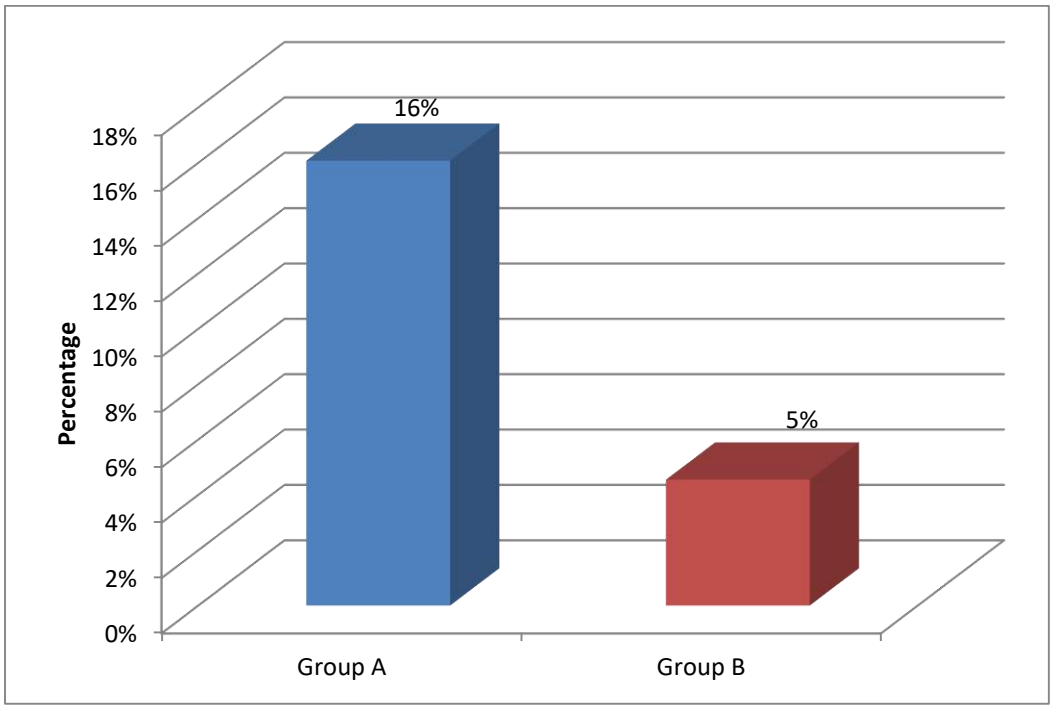


Figure 34: Comparison of admission in NICU in group A and group B.

Table 42: Comparison of admission NICU in group C and group D.

		Group C		Group D		Total	Chi-square value	p-value
		n=42	%	n=29	%			
Admission To NICU	yes	7	17%	2	7%	9	1.479	0.224
	No	35	83%	27	93%	62		

In group C, 17% (n=7) patients were admitted in NICU as compared to group D, in which 7% (n=2) patients were admitted in NICU. The p value was 0.224 which was not statistically significant

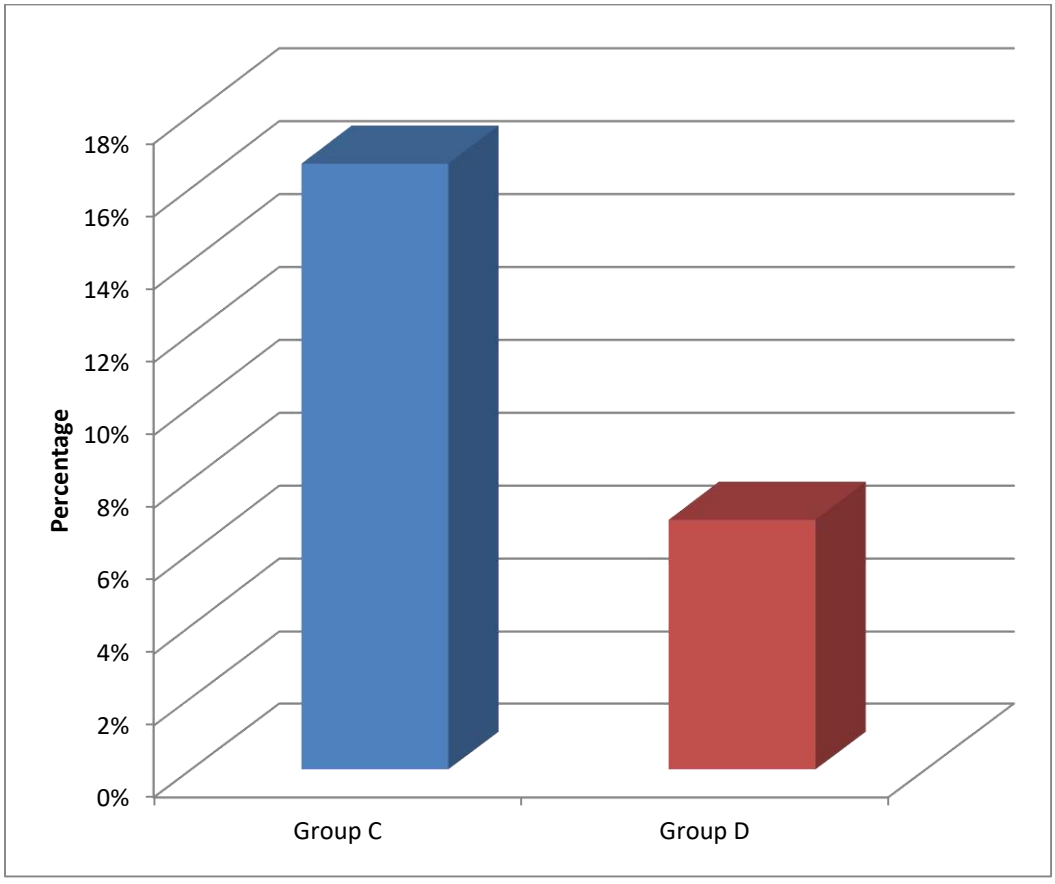


Figure 35: Comparison of admission NICU in group C and group D.

A. Comparison between indications for admission to NICU in group A and group B

Table 43: Comparison between indications for admission to NICU in group A and group B.

		Group A		Group B				
		n=56	(%)	n=44	(%)	Total	Chi-square value	p-value
Indication of admission	Meconium aspiration	3	33%	0	0%	3	4.912	0.296
	Transient tachypnea	2	22%	0	0%	2		
	Perinatal asphyxia	3	33%	1	50%	4		
	Others	1	11%	1	50%	2		

In group A, 33% (n=3) admissions were due to meconium aspiration. 11% (n=1) were other causes, 33% (n=3) was perinatal asphyxia and 22% (n=2) was due to transient tachypnea of new born. In Group B, none of the babies had meconium aspiration or transient tachypnea of newborn, 50% (n=1) babies were admitted due to perinatal asphyxia and 50% (n=1) babies were admitted due to other causes.

The p value was 0.296 was not statistically significant in both the groups.

The most common indication of admission was meconium aspiration and perinatal asphyxia in group A, whereas perinatal asphyxia and other causes was the most common indication in group B

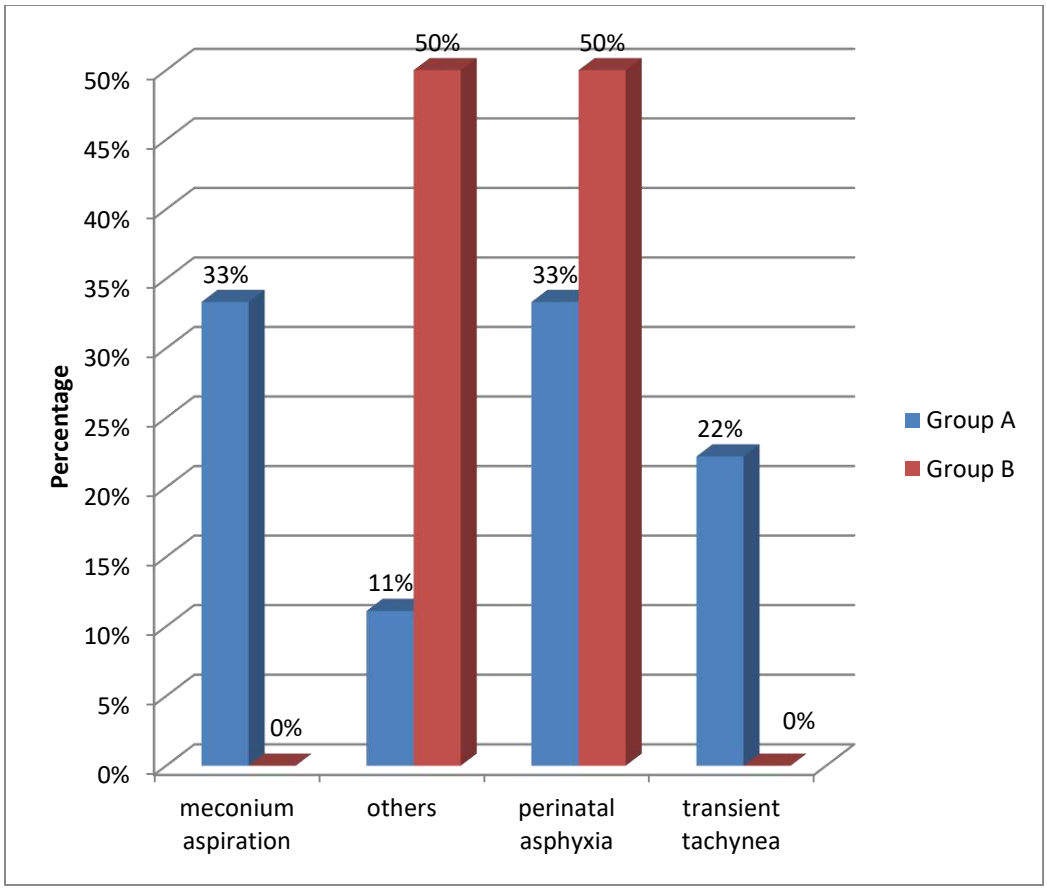


Figure 36: Comparison of babies admitted in NICU between two groups.

B. Comparison between indications for admission to NICU in group C and group D

Table 44: Comparison between indications for admission to NICU in group C and group D.

		Group C (n=7)		Group D (n=2)		Total	Chi-square value	p-value
		n.	%	n	%			
Indication of admission	Meconium aspiration	3	43%	0	0%	3	3.089	0.543
	Transient tachypnea	1	14%	0	0%	1		
	Perinatal asphyxia	2	29%	1	50%	3		
	Others	1	14%	1	50%	2		

Out of the total number of admissions in NICU, In group C, 43% (n=3) admissions were due to meconium aspiration. 14% (n=1) were other causes, 29% (n=2) was perinatal asphyxia and 14% (n=1) was due to transient tachypnea of new born. In Group D, none of the babies had meconium aspiration or transient tachypnea of newborn, 50% (n=1) babies were admitted due to perinatal asphyxia and 50% (n=1) babies were admitted due to other causes.

The p value was 0.543 was not statistically significant in both the groups.

The most common indication of admission was meconium aspiration and perinatal asphyxia in group A, whereas perinatal asphyxia and other causes was the most common indication in group B

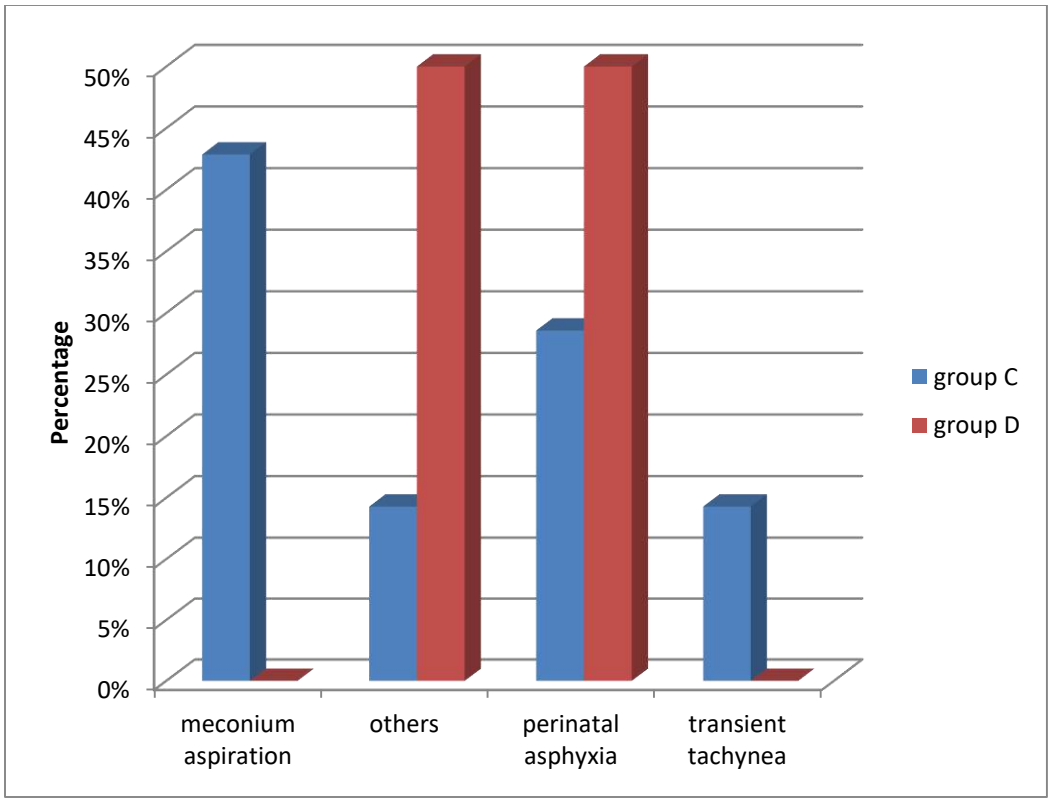


Figure 37: Comparison between indications for admission to NICU in group C and group D.

DISCUSSION

Labour induction is a common practice in obstetrics. Labour can be induced for various fetomaternal indications when the benefits of induction outweigh its risks. There are many methods by which labour induction can be carried out. Out of these, the use of prostaglandins has shown to increase the likelihood of vaginal delivery[5]. The different preparations of prostaglandins: gel, pessary and tablet form are highly efficacious for use in cervical ripening and induction of labour. The intracervical gel form has been in use for many years, but it requires repeated vaginal examinations and repeated dosing.

The dinoprostone pessary has been introduced as a better delivery system with the advantage of a 24 hour sustained release and rapid removal of the pessary when needed. This study has been conducted to compare the effect of inducing agents dinoprostone sustained release vaginal pessary and intracervical gel on labour and its fetomaternal outcome.

In this study out of the total number of 100 patients, those who received the intravaginal pessary formed group A and those who received the gel formulation formed group B. The outcome in both the groups was assessed using the modified bishops score; with an MBS > 6 considered as successful induction. The patients in group A undergoing successful induction formed group C; whereas those undergoing successful induction in group B formed group D respectively. These groups were further assessed for various fetal and maternal parameters.

DEMOGRAPHIC PARAMETERS

In our study, out of a total of 100 patients, the mean age of induction of group A and B was 28.75 and 28.77 years respectively. Among the patients that had successful induction, the mean age was 28.4 years in group C, and 29.1 years in group D respectively. A majority of the patients belonged to the age group of 26-30 years. There was no statistically

significant difference in the ages between the groups. Hence, age did not seem to be a significant factor influencing the success of induction.

In a study by Kalkat et al in 2008, a randomized controlled trial was conducted to compare the clinical efficacy and cost-effectiveness of Dinoprostone Slow Release Pessary with Gel for induction of labour at term. The mean age in their study was 27 years[45]. The mean age in their study is comparable to the mean age of induction of our study.

Rayamajhi et al, in 2009 aimed to study the incidence and indications for labour induction and study the predictors of failed induction. He found that maternal age was a variable that was analyzed as a risk factor for failed induction. Women above 30 years (n=39) had a higher failure rate (n=21, 53.84%) as compared to women aged 30 years or less (n=117) in whom 28.2% (n=33) women had failed induction. He documented that advanced maternal age as a risk factor for unsuccessful induction[58].

RCOG, 2013 states that advanced maternal age is associated with higher obstetric complications and decreased number of vaginal deliveries. Complications such as low birth weight, placenta previa, abruption, mal presentation, post term delivery and still births are more commonly seen in women more than 40 years of age[59].

Giugliano et al, conducted a prospective observational study from January 2009 to December 2011 with 248 patients to assess the factors that influence the failure of labour induction. They found that maternal age was one of the independent significant variables (p = 0.01, OR 1.08) determining the risk of cesarean delivery. These observations are in contrast to our study[60].

In our study, a majority of the patients belonged to upper socio-economic class. This comprised of 38% patients in group A and 36%patients in group B. Amongst the patients who had sucessful induction, 40% patients in group C and 41% (n=12) patients in group D belonged to upper socio-economic class. The distribution of data between all the groups was similar.

Socioeconomic status did not have an effect on induction of labour.This is can be explained by the fact our hospital is a tertiary care hospital giving optimum quality of care to patients belonging to all socio-economic classes.

Carter et al in 2020 conducted a study to asses socioeconomic factors such as maternal educational attainment, marital status, and electoral ward deprivation for labour induction. Patients living in less advantaged areas and with lower level of education were more likely to undergo induction. (OR: 1.393, CI: 1.112, 1.745, p=0.004). They documented that to the best of their knowledge, no previous research had examined the relationship between maternal and socioeconomic status and labour augmentation[61].

In our study, majority of the patients; 82% versus 70 % patients were booked in group A and group B respectively and received optimal antenatal care. There was no satatistically significant difference between the groups. Majority of the patients in both the groups were booked, with patients in each group having adequate knowledge about the induction process and mode of delivery. Hence, the quality of antenatal care did not differ between the groups.

Milcent and Zibri published a study in 2018 in health economics review, in which they examined the impact of prenatal care utilization on cesarean delivery rates. They found that Women attending prenatal education may be more aware of the risks of cesarean deliveries and less affected by fear of giving birth, and may therefore ask less often for a cesarean delivery. They emphasized the importance of focusing on pregnancy health education, particularly for low-income women, as a potential way to limit unnecessary cesarean deliveries[62]. These findings were in contrast to our study.

MATERNAL PARAMETERS

In our study, all the patients enrolled were beyond 37 weeks of gestation. In group A, majority 30% (n=17) patients were induced at 38-38^{+6} weeks

as compared to group B, in which majority of patients ,36% (n=16) were induced at 37-37^{+6} weeks of gestation. In group C, 33% (n=14) patients and 41% (n=12) patients in group D in the gestation 37 to 37^{+6} weeks had sucessful induction. The gestational age for induction was similar between the groups.

In a study was conducted by Garg et al in 2018, to compare the clinical efficacy of dinoprostone sustained release vaginal pessary and intracervical gel for induction of labour on first 100 patients of each group. He found that there was no statistically significant difference between the two groups in parity, gestational age and indications for induction of labour and also in induction to delivery interval[53]. This was comparable to our study.

Rayamajhi et al, in 2009 found that failed induction was higher in the 37-38 weeks (n=6; failure rate: 50%) and >41 weeks gestational age group (n=32; failure rate: 56.3%) respectively. At 38-39 weeks pregnancy (n=38), the failure rate was 28.9% (n=11), while at 39-40 weeks pregnancy (n=32), 28.1% (n=9) had failed induction and at 40-41 weeks pregnancy (n=48), 31.25% (n=13) required Caesarean delivery[58]. Hence, successful induction was noted to be higher between 38-41 weeks gestational age in this study.

Bassety et al, in June 2017 studied the indications and outcomes of failed induction in primigravidae in a tertiary care hospital located in a poor resource setting. He found that gestational age >41 weeks was associated with increased rates of failed induction[63]. However, he documented that there are less number of studies comparing the effect of gestational age with success of induction of labour. This is because induction of labour, depends on many other factors interacting during labour which are not necessarily related to the induction process.

Multiparity is a known factor to predict successful induction. Cervical dilation rates are faster in multiparous as compared to nulliparous women. In our study in groups A and C, majority of the patients were primigravida

(72% versus 81%); in groups B and D, majority of patients were multigravida (76% versus 72%). The p value was 0.001, indicating a significant difference between the two groups. This can be explained the fact that there was random distribution of patients between the groups. Out of the two groups, higher rate of successful induction was seen in primigravida who were induced with pessary as compared to multigravidas who responded better with gel preparation. However, as the sample size of our study is small, the effect of parity on the success of induction of labour could not be determined.

Juhasova et al conducted a study in 2018 to assess cervical dilation rates of nulliparous and multiparous women in the active first stage of labour and to evaluate significant impact factors. He found that cervical dilation were faster in multiparous as compared with nulliparous women (p value < 0.001)[64].

In a study by Zhao et al, in 2017 to identify relevant factors for vaginal delivery among women who underwent labour induction with vaginal dinoprostone (PGE2) insert in a Chinese tertiary maternity hospital. He concluded that higher parity (multiparous versus nulliparous, p<.001, OR ¼ 6.57, 95%CI 2.37–18.23) was associated with a higher rate of successful delivery within 24 hours[51].

Khan et al, conducted a study in 2009 to assess the factors associated with failed induction of labour in a secondary care hospital. He found that failed induction rate was 4.6 times higher in nulliparous patients (25.3%) as compared to their multiparous counterparts (6.8%)[65].

In contrast to the above studies, Garg et al, in 2018 found that there was insignificant difference in terms of parity between the two groups (p value = 0.229)[53].

In our study, out of a total 100 patients, 52% (n=29) patients in group A, 61% (n=27) patients in group B, 69 % (n=29) patients in group C and 83% (n=24) patients in group D had vaginal delivery. There was no statistically significant difference between the groups in the mode of delivery.

In the study by Garg et al, in 2018 the difference in caesarean section rate among nulliparous and multiparous patients using vaginal pessary or intracervical gel was not statistically significant (p value being 0.229)[53]. In a similar study by Kalkat et al, in 2008 he compared the dinoprostone slow release pessary with gel for induction of labour. He found that the number of vaginal deliveries within 24 hours after induction in two groups was comparable (pessary 63.3% versus gel 66.6%)[45].

Kho et al conducted a study of 969 women in the year 2008, to compare the efficacy and safety of controlled-release dinoprostone vaginal pessary with dinoprostone intravaginal gel for induction of labour. There was no difference in rates of mode of birth between pessary and gel groups[46]. The results of these studies were comparable to our study, indicating that both the preparations of prostaglandins used were equally efficacious.

Kumari et al, in 2018 did a comparative study on outcome of induction of labour in term primigravidae women with repeated gel and long acting vaginal inserts. There was a significant difference in the number of women requiring instrumental delivery, with those receiving gel more likely to need assisted vaginal delivery (RR 3.0, 95% CI 1.1–8.4, P = 0.04)[55].

Triglia et al, in 2010 to compared 24-hour controlled-release vaginal dinoprostone pessary versus gel for induction of labour at term in women with an unfavorable cervix. The rate of spontaneous vaginal delivery was significantly higher in the pessary group (72%) than in the gel group (54%)[47]. Both the 24-hour dinoprostone vaginal pessary and gel appear to be safe for labour induction. These findings were in contrast to our study.

INDUCTION OF LABOUR

Labour can be induced for various conditions such as pre labour rupture of membranes, preeclampsia, gestational diabetes, post datism, fetal growth restriction, intrahepatic cholestasis of pregnancy and other indications. Induction should be carried when the risks of continuation of pregnancy are more than its termination. In our study, in group A, a majority of

patients were induced for postdatism, and in group B, majority patients were induced for intrahepatic cholestasis of pregnancy and decreased fetal movements each. In studies by Kumari et al, Kho et al, and Triglia et al post datism was the most common indication for induction of labour[46, 47, 55].

Modified bishop's score comprises of various parameters such as cervical consistency, dilation, length, position and station of the head. Successful induction is defined by an MBS > 6. In our study, successful induction was considered by a MBS > 6. Out of a total 100 patients in our study, 71 of them had successful induction. 75% patients in group A and 66% patients in group B had successful induction. This difference was not statistically significant (p value 0.320). This suggests that both the pessary and gel form did not differ in the rates of achieving successful induction.

Triglia et al, observed that successful induction was considered if active labour was established within 48 hours from administration of drug. Active labour was taken as at least four regular uterine contractions during a 10-minute period, and the cervix was effaced and 3 cm dilated. The spontaneous vaginal delivery rate was 75% in the insert group and 50% in the gel group. Based on 0.8 power to detect a significant difference (p = 0.05)[47]. They demonstrated that in women with a Bishop score < 4, a protocol of induction of labour with a vaginal dinoprostone pessary applied for 24 hours achieves a significantly higher rate of spontaneous vaginal delivery. This observation was in contrast to our study.

Oxytocin can be used for both induction and augmentation of labour. In our study, patients with an MBS equal to or more than 6 were assessed for the need of oxytocin for augmentation of labour. In group A, 36% (n=20) patients as compared to 30% (n=13) patients in group B required oxytocin. The need of oxytocin in both the groups was similar; with majority of patients not requiring it.

WHO in 2011 stated that, the use of oxytocin alone was associated with decreased chances of vaginal birth as compared to its combination with prostaglandins. (RR 1.77, 95% CI 1.31–2.38)[1].

Kho et al conducted a study in 2008 in which he compared the efficacy and safety of controlled-release dinoprostone vaginal pessary with dinoprostone intravaginal gel for induction of labour. He found no difference in the need for oxytocin augmentation between the two groups[46]. These findings were comparable to our study.

In a study by Garg et al, in 2018, to compare the clinical efficacy of dinoprostone gel with pessary for induction of labour. He found that the need of oxytocin was higher in intracervical gel group (72%) as compared to the vaginal pessary group (51%). The p value being 0.002[53].

Facchinetti et al, in 2012 conducted a metanalysis to assess the efficacy and safety of the dinoprostone vaginal insert compared to repeated prostaglandin administration. The need for oxytocin was reduced with the use of vaginal insert (RR = 0.64, 95% CI = 0.42, 0.99)[48]. This was in contrast to our study.

ACOG in 2009 defines good intensity contractions as five contractions or less in 10 minutes, averaged over a 30-minute window[5]. In our study, the average time interval between induction of labour and onset of good contractions has been studied. It averaged to about 12.07 hours in group A, as compared to 12.28 hours in group B. The average time interval between the start of induction and time of delivery was also evaluated. It averaged about 17.87 hours in group A, and 16.16 hours in group B. Both time intervals were comparable between the two groups. In our study, none of the preparations resulted in a quicker delivery than the other. Studies conducted by Garg et al in 2018, and Kalkat et al in 2008 had results that were comparable to our study[45, 53].

In contrast our study, in a study in by Kumari et al in 2018, the mean time to delivery for all women showed a statistically significant difference, with women receiving gel preparation delivering earlier on an average than

those receiving the pessary preparation (21.1 versus 29.6 hours p = 0.018)[55]. This difference was seen irrespective of the mode of delivery.

The safety outcome of both the preparations of prostaglandins was assessed as development of adverse events such as uterine hyper stimulation, postpartum hemorrhage, retained placenta, meconium stained liquor, fetal distress and uterine rupture. This shows that both the preparations were safe for use for induction of labour.

ACOG, 2009 defines uterine hyper stimulation (tachysystole) as more than five contractions in ten minutes, in a 30 minute window[5]. This is a known side effect of prostaglandin preparations used for induction of labour. In our study, none of the patients had uterine hyper stimulation. The incidence of adverse events such as meconium stained liquor, postpartum hemorrhage, fetal distress, and retained placenta in our study was comparable between the two groups. There were no cases of uterine rupture. This shows that both the preparations were safe for use. Comparable to our study, Garg et al in 2018 observed no difference in the number of patients with adverse effects in the gel and pessary groups (p value 00.866)[53]. None of the patients in our study reported spontaneous expulsion of the pessary.

In contrast to our study, Facchinetti et al stated that the risk of hyper stimulation was statistically higher in nulliparous women using vaginal insert than the other ways of administration with RR = 2.17, 95% CI = 1.08,4.33. (48). Kho et al in 2008, documented that hyper stimulation (14 (2.9%) vs 2 (0.4%), RR 6.5 (1.5–28.9)) was more common in women who received the pessary versus gel. In above studies the use of pessary preparation was associated with a higher incidence of uterine hyper stimulation[46].

In our study, the number of per vaginal examinations from the start of induction till delivery were noted. It was observed that the average number of per vaginal examinations was 5.57 in group A as compared to 8.89 in group B (p value = 0.000). In patients with successful induction, the

average number of per vaginal examinations was 6.02 in group C as compared to 8.14 in group D (p value was 0.000). A statistically significant difference was noted between the groups with patients receiving the gel preparation requiring a higher number of per vaginal examinations as compared to pessary. This can be attributed to the 24 hour sustained release formulation of pessary as compared to repeated dosing of the gel form, necessitating the need for a vaginal examination.

Kalkat et al in 2008, compared the dinoprostone slow release pessary with gel for induction of labour. He found that the number of vaginal examinations performed were significantly higher in the gel group (gel 6.2+2.7 versus Pessary 5.0+2.2, p¼0.012) compared with Pessary[45]. Devdatt. L. Pitale in 2017, assessed the effectiveness of dinoprostone vaginal pessary in induction of labour at term. He found that dinoprostone vaginal pessary was a highly effective method for induction of labour at term. It reduced consistently the number of internal examinations, reducing the risk of ascending infections and maternal anxiety during induction of labour[52]. This was comparable to our study.

In our study, the patient satisfaction was subjectively assessed on a scale of 0 to 10, with 0 being the least level of satisfaction and 10 being the highest. The average score of patients in group A was 8.14 as compared to group B where it was 7.25 (p value was 0.000). In the patients with successful induction, the average patient satisfaction score was 8.07 in group C as compared to 7.28 in group D. (p value was 0.003). This indicates a statistically significant difference between the groups, suggesting a higher level of patient satisfaction with the pessary form. This can be attributed to the fact that the use of pessary requires less number of vaginal examinations making it more comfortable and convenient for the patient. However, to the best of my knowledge there are no studies comparing the prostaglandin preparations with the level of patient satisfaction.

FETAL PARAMETERS

In our study, all women had live births, the mean fetal birth weight in group A was 3043.57 grams and group B was 2943.86 grams respectively. In patients with successful induction, the mean fetal birth weight was 3017.38 and 2856.90 grams in group C and group D respectively. There was statistically no significant difference between the groups.

In a study conducted by Khan et al in 2009, to assess the factors associated with failed induction of labour in a secondary care hospital. It was also observed that women having failure of induction were 2.5 times more at odds of having macrosomic babies (3.8%) than patients with successful inductions (1.5%)[65]. However in our study, we found no such differences.

The Apgar scores at 1 minute and 5 minutes was noted in the two groups. 84% (n=47) of neonates in group A had Apgar scores of more than 8 at one minute, 93% (n=52) had Apgar scores of 9 at 5 minutes. In group B, 93% (n=41) neonates had an Apgar score of 8 at 1 minute, and 93% (n=41) neonates had an Apgar score of 9 at 5 minutes. In group C and D the Apgar scores were similar. Our study did not find any differences between the groups in terms of Apgar scores at 1 minute and 5 minutes. This indicates that both the agents are safe for the fetus.

Comparable to our study, Triglia et al in 2010, conducted a study to compare 24-hour controlled-release vaginal dinoprostone pessary versus gel for induction of labour. They found that no cases of 5-minute Apgar scores <7 were present in either of the groups, indicating both methods to be safe for induction of labour[47]. Gulmezoglu et al in 2014 conducted a study on induction of labour for improving birth outcomes for women at or beyond term. They observed that labour induction was associated with lesser perinatal deaths (risk ratio (RR) 0.31, 95% confidence interval (CI) 0.12 to 0.88). There was no significant difference between the rates of Apgar scores less than seven at five minutes (RR 0.72, 95% CI 0.44 to 1.18)[66]. These findings were similar to our study. This indicates that both

formulations of the drug resulted in good perinatal outcome indicating that both formulations are safe and effective inducing agents.

In our study, 16% (n=9) versus 5% (n=2) patients in groups A and B required NICU admission, whereas in groups C and D, 17% (n=7) and 7% (n=2) patients required it. There was no statistically significant difference in the number of NICU admissions in both the groups. Various indications of admissions into NICU were assessed, such as perinatal asphyxia, meconium aspiration, transient tachypnea and others. They did not have a significant effect on induction. The results were comparable between the groups. In our study, none of the groups showed an increased rate of perinatal complications indicating that both formulations are safe inducing agents.

Kandemir et al, in 2015 found that the number of admissions to NICU were similar in multiparous and nulliparous group receiving dinoprostone[50]. Cochrane review (2018) has shown that timely induction of labour lowers the rates of neonatal intensive care unit (NICU) admission, (RR 0.88, 95% CI 0.77 to 1.01) with fewer babies having Apgar scores less than seven at five minutes in the induction groups compared with expectant management (RR 0.70, 95% CI 0.50 to 0.98)[66]. This is comparable to our study where timely induction was planned for all the patients and majority of the babies had good Apgar scores at birth.

SUMMARY AND CONCLUSION

1. A prospective randomised study conducted from 1st January 2019 in which patients were followed for outcome till 31st December 2019.
2. Patients were divided into 2 groups, Group A (receiving pessary) and group B (receiving gel)
3. Induction was considered as successful when the MBS was more than 6 in 24 hours.
4. To compare the fetomaternal outcome, patients in whom induction was successful were further sub- divided two groups. Patients who were induced with pessary and had successful induction formed group C, while those induced with the intracervical gel and had successful induction formed group D.
5. Most of the patients in our study belonged to the age group of 26-30 years . The age at which induction was carried out was not significatly correlated with the success of induction in our study.
6. A majority of our patients were booked and belonged to upper socioeconomic class.
7. All patients were enrolled for induction of labour after 37 weeks of gestation. The gestational age at which labour was induced was comparable between the two groups
8. A higher rate of successful induction was seen in primigravidas who were induced with pessary as compared to multigravidas who responded better with gel preparation. This can be explained by the random distribution of patients between the groups. The effect of parity on induction of labour could not be determined as the sample size of our study was small.
9. Most of the patients in our study delivered vaginally in both the groups.
10. Post datism was the most common indication for induction of labour in group A, whereas intrahepatic cholestasis of pregnancy and

decreased fetal movements were the common indications for induction in group B.

11. There was no statistically significant difference in successful induction between the pessary and gel group. This indicates that both the preparations of drug are equally efficacious.
12. There was no significant relationship among patients with successful induction in terms of age, socioeconomic status, or period of gestation.
13. The need of oxytocin for labour augmentation was found to be similar in patients with successful induction in both gel and pessary groups, with majority of patients not requiring oxytocin.
14. The average time taken from instillation of drug to the onset of good uterine contractions and the time interval between instillation of drug and delivery was comparable between the two groups.
15. No statistically significant difference was seen in adverse events in both the groups. Pessary could be rapidly removed in case of any adverse events.
16. Number of per vaginal examinations were significantly higher with the gel form as compared to the pessary. This may be attributed to repeated dosing of the drug.
17. Patient satisfaction was significantly higher in those receiving the pessary form. This was probably because it is more comfortable, has lesser number of vaginal examinations reducing maternal anxiety.
18. All the patients in our study had live births. We found no difference in the mean fetal birth weights and the Apgar scores between the groups.
19. No statistically significant difference in NICU admission was noted in both the groups.

The strength of our study lies with favorable maternal and neonatal outcome. It shows that both the preparations of dinoprostone are safe and efficacious for use in terms of maternal and fetal outcomes.

We conclude that both the intravaginal pessary and intracervical gel are equally safe and efficacious for their use for induction of labour. The pessary form offers an advantage of lesser number of vaginal examinations, thus reducing maternal anxiety and reducing the risk of ascending infections. It appears to be more comfortable for the patients. However, more studies are needed to evaluate the cost effectiveness between the two preparations.

LIMITATIONS

There are many limitations to our study, the sample size is small. There is no blinding amongst the two drug preparations offered for induction of labour. The cost effectiveness of the two preparations needs to be studied.

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S NO.	INITIALS	MRD	AGE	SOCIO-ECONOMIC STATUS	BOOKED	UNBOOKED/ BOOKED OUTSIDE	PERIOD OF GESTATION	PERIOD OF GESTATION GROUP	PRIMIGRAVIDA	MULTIGRAVIDA	SINGLETON PREGNANCY	INDICATION FOR INDUCTION OF LABOR_POSTDATISM	PPROM>24 HRS	PREECLAMPSIA	INTRAHEPATIC CHOLESTASIS OF PREGNANCY	GESTATIONAL DIABETES	FETAL GROWTH RESTRICTION	DECREASED FETAL MOMENTS
1	CK	688175	29	LM	YES	-	38 PLUS 4	2	YES	-	YES	-	-	-	-	-	YES	-
2	N	596194	28	M	YES	-	39 PLUS 2	3	YES	-	YES	-	-	-	-	-	-	YES
3	JK	271945	29	U	YES	-	40	4	YES	-	YES	YES	-	-	-	-	-	-
4	BK	90309	30	LM	-	YES	38	2	-	YES	YES	-	YES	-	-	-	-	-
5	SM	586698	27	U	YES	-	37 PLUS 5	1	YES	-	YES	-	-	-	-	-	YES	-
6	MJ	661480	30	M	YES	-	39 PLUS 5	3	YES	-	YES	-	-	-	-	-	-	YES
7	T	660987	25	U	YES	-	40	4	YES	-	YES	YES	-	-	-	-	-	-
8	N	6718	31	M	YES	-	37	1	-	YES	YES	-	-	-	-	-	YES	-
9	SD	646993	33	LM	YES	-	38 PLUS 6	2	YES	-	YES	-	-	-	-	-	-	-
10	R	509603	28	U	YES	-	37 PLUS 4	1	YES	-	YES	-	-	YES	-	-	-	-
11	MS	521656	35	M	YES	-	37 PLLUS 5	1	-	YES	YES	-	-	YES	-	-	-	-
12	KK	308591	32	M	YES	-	37 PLUS 4	1	-	YES	YES	-	-	-	-	-	-	-
13	P	535086	27	M	YES	-	39 PLUS 4	3	YES	-	YES	-	YES	-	-	-	-	-
14	P	722181	32	U	YES	-	39 PLUS3	3	YES	-	YES	-	-	-	-	-	-	-
15	I	7690	26	U	YES	-	38 PLUS 5	2	-	YES	YES	-	-	-	-	YES	-	-
16	MK	723915	24	LM	YES	-	39 PLUS 5	3	-	YES	YES	-	-	-	-	-	-	-
17	M	8080	33	M	-	YES	37	1	-	YES	YES	-	-	-	YES	-	-	-
18	SP	156646	28	U	-	YES	37 PLUS 2	1	-	YES	YES	-	-	YES	-	-	-	-
19	K	585237	34	U	YES	-	38 PLUS 6	2	YES	-	YES	-	-	-	-	YES	-	-
20	M	725499	28	LM	-	YES	38	2	YES	-	YES	-	-	-	YES	-	-	-
21	A	555898	26	M	YES	-	40	4	YES	-	YES	YES	-	-	-	-	-	-
22	H	731199	27	U	YES	-	38 PLUS 1	2	YES	-	YES	-	-	-	-	-	-	-
23	MA	696539	24	U	YES	-	39 PLUS 3	3	YES	-	YES	-	-	-	-	-	-	YES
24	P	731310	29	LM	YES	-	37 PLUS 3	1	-	YES	YES	-	-	-	YES	-	-	-
25	AS	630723	28	M	YES	-	38 PLUS 6	2	-	YES	YES	-	YES	-	-	-	-	-
26	PD	336477	29	U	YES	-	39 PLUS1	3	-	YES	YES	-	-	-	-	-	-	YES
27	MJ	735635	29	U	YES	-	37 PLUS 1	1	-	YES	YES	-	-	-	YES	-	-	-
28	JK	62521	25	LM	YES	-	37 PLUS 6	1	YES	-	YES	-	-	-	-	-	YES	-
29	SJ	739144	26	M	YES	-	37 PLUS 5	1	YES	-	YES	-	-	-	-	-	YES	-
30	KK	741792	39	U	YES	-	38 PLUS 1	2	-	YES	YES	-	YES	-	-	-	-	-
31	MS	602816	27	M	YES	-	39 PLUS 1	3	YES	-	YES	-	-	-	-	-	-	YES
32	SK	623773	22	M	-	YES	37	1	-	YES	YES	-	-	YES	-	-	-	-
33	RK	550184	25	LM	YES	-	37 PLUS 6	1	YES	-	YES	-	-	-	YES	-	-	-
34	K	514702	25	LM	YES	-	39 PLUS 2	3	YES	-	YES	-	-	-	-	-	-	YES
35	P	775635	29	U	-	YES	39 PLUS 5	3	-	YES	YES	-	-	-	-	-	-	YES
36	HK	618083	30	LM	YES	-	39	3	YES	-	YES	-	-	-	-	YES	-	-
37	JB	490641	26	U	YES	-	39 PLUS 5	3	YES	-	YES	YES	-	-	-	-	-	-
38	SM	778412	29	LM	YES	-	38 PLUS 1	2	YES	-	YES	-	-	-	-	YES	-	-
39	N	742009	27	LM	YES	-	40 PLUS 1	4	YES	-	YES	YES	-	-	-	-	-	-
40	N	778247	40	M	YES	-	40 PLUS 1	4	YES	-	YES	YES	-	-	-	-	-	-
41	NG	63172	33	U	YES	-	37 PLUS 3	1	-	YES	YES	-	-	-	YES	-	-	-
42	R	440090	27	LM	YES	-	38 PLUS 2	2	-	YES	YES	-	YES	-	-	-	-	-
43	SV	136652	35	M	YES	-	37 PLUS 6	1	-	YES	YES	-	-	YES	-	-	-	-
44	GS	784545	28	U	YES	-	38 PLUS 5	2	YES	-	YES	-	-	-	-	YES	-	-
45	SA	401220	28	M	YES	-	37 PLUS 1	1	-	YES	YES	-	-	-	-	-	YES	-
46	AK	118006	24	U	YES	-	39 PLUS 5	3	YES	-	YES	YES	-	-	-	-	-	-
47	M	766955	30	LM	-	YES	37	1	YES	-	YES	-	-	YES	-	-	-	-
48	SA	721366	28	M	YES	-	38 PLUS 1	2	YES	-	YES	-	-	-	-	YES	-	-
49	TG	775466	27	LM	-	YES	37 PLUS 1	1	YES	-	YES	-	-	-	YES	-	-	-
50	RK	655240	27	U	YES	-	40 PLUS 1	4	YES	-	YES	YES	-	-	-	-	-	-

S NO.	INITIALS	MRD	OTHERS	DRUG USED	GROUP	TIME INTERVAL BETWEEN INSTILLATION OF DRUG AND ONSET OF GOOD CONTRACTIONS	TIME OF DELIVERY	CERVIPRIME GEL MBS AT START OF INDUCTION	FIRST DOSE	SECOND DOSE	THIRD DOSE	PESSARY MBS AT START OF INDUCTION	AFTER 24 HRS	WAS INDUCTION SUCCESSFUL	NUMBER OF PV EXAMINATIONS	NEED OF OXYTOCIN	MODE OF DELIVERY VAGINAL DELIVERY	VD WITH FORECEPS	CESAREAN SECTION
1	CK	688175	-	CERVIPRIME	1	18	22	2	2	4	5	-	-	NO	11	-	-	YES	-
2	N	596194	-	PROPESS	0	-	9	-	-	-	-	3	NA/CS	NO	4	-	-	-	YES
3	JK	271945	-	CERVIPRIME	1	17	20	3	3	5	NA/INST	-	-	YES	12	-	-	YES	-
4	BK	90309	-	CERVIPRIME	1	4	6	5	5	NA/VD	-	-	-	YES	8	YES	YES	-	-
5	SM	586698	-	PROPESS	0	-	13	-	-	-	-	3	NA/CS	NO	3	-	-	-	YES
6	MJ	661480	-	PROPESS	0	8	22	-	-	-	-	2	7	YES	5	-	-	-	YES
7	T	660987	-	PROPESS	0	7	9	-	-	-	-	4	6	YES	4	YES	YES	-	-
8	N	6718	-	CERVIPRIME	1	10	12	5	5	5	NA/ INS	-	-	YES	10	-	-	YES	-
9	SD	646993	YES	PROPESS	0	16	21	-	-	-	-	2	6	YES	6	YES	-	YES	-
10	R	509603	-	PROPESS	0	-	19	-	-	-	-	4	NA/CS	NO	3	-	-	-	YES
11	MS	521656	-	CERVIPRIME	1	7	10	3	3	6	-	-	-	YES	12	-	YES	-	-
12	KK	308591	YES	CERVIPRIME	1	6	11	4	4	6	-	-	-	YES	9	-	YES	-	-
13	P	535086	-	PROPESS	0	11	14	-	-	-	-	3	8	YES	4	YES	YES	-	-
14	P	722181	YES	PROPESS	0	12	17	-	-	-	-	5	7	YES	6	YES	YES	-	-
15	I	7690	-	CERVIPRIME	1	8	11.5	4	4	5	NA/VD	-	-	YES	9	YES	YES	-	-
16	MK	723915	YES	PROPESS	0	7	12	-	-	-	-	3	NA/VD	YES	5	-	YES	-	-
17	M	8080	-	CERVIPRIME	1	9	12	4	4	5	NA/VD	-	-	YES	9	YES	YES	-	-
18	SP	156646	-	CERVIPRIME	1	18	22.5	2	3	4	6	-	-	YES	11	YES	YES	-	-
19	K	585237	-	PROPESS	0	9.5	13.5	-	-	-	-	5	NA/VD	YES	4	YES	YES	-	-
20	M	725499	-	PROPESS	0	11	17	-	-	-	-	4	6	YES	3	-	-	-	YES
21	A	555898	-	PROPESS	0	18	22	-	-	-	-	3	6	YES	4	YES	YES	-	-
22	H	731199	YES	PROPESS	0	-	10	-	-	-	-	3	NA/CS	NO	2	-	-	-	YES
23	MA	696539	-	PROPESS	0	10	12.5	-	-	-	-	5	7	YES	5	YES	-	-	YES
24	P	731310	-	CERVIPRIME	1	8	10.5	3	3	NA/VD	-	-	-	YES	3	-	YES	-	-
25	AS	630723	-	CERVIPRIME	1	15	19	4	4	5	NA/VD	-	-	YES	6	-	YES	-	-
26	PD	336477	-	CERVIPRIME	1	17	20	4	4	6	-	-	-	YES	12	-	-	YES	-
27	MJ	735635	-	CERVIPRIME	1	18	24	4	4	5	NA/VD	-	-	YES	7	YES	YES	-	-
28	JK	62521	-	CERVIPRIME	1	24	28	3	4	5	5	-	-	NO	13	YES	YES	-	-
29	SJ	739144	-	PROPESS	0	6	9	-	-	-	-	3	NA/VD	YES	7	-	YES	-	-
30	KK	741792	-	PROPESS	0	7	11	-	-	-	-	4	7	YES	4	-	YES	-	-
31	MS	602816	-	CERVIPRIME	1	26	32	3	3	5	5	-	-	NO	12	-	YES	-	-
32	SK	623773	-	CERVIPRIME	1	-	24	2	2	3	5	-	-	NO	10	-	-	-	YES
33	RK	550184	-	PROPESS	0	9	14	-	-	-	-	4	NA/VD	YES	6	-	YES	-	-
34	K	514702	-	PROPESS	0	9	14.5	-	-	-	-	5	6	YES	5	YES	YES	-	-
35	P	775635	-	CERVIPRIME	1	17	20	5	6	NA/VD	-	-	-	YES	8	-	YES	-	-
36	HK	618083	-	CERVIPRIME	1	18	21	2	2	3	5	-	-	NO	14	YES	YES	-	-
37	JB	490641	-	CERVIPRIME	1	-	14	4	4	6	-	-	-	YES	9	-	-	-	YES
38	SM	778412	-	PROPESS	0	21	28	-	-	-	-	4	6	YES	5	YES	YES	-	-
39	N	742009	-	PROPESS	0	16	19	-	-	-	-	3	6	YES	5	-	YES	-	-
40	N	778247	-	PROPESS	0	-	19	-	-	-	-	3	NA/CS	NO	2	-	-	-	YES
41	NG	63172	-	PROPESS	0	6	13	-	-	-	-	4	7	YES	5	YES	YES	-	-
42	R	440090	-	CERVIPRIME	1	6	11.5	5	5	NA/VD	-	-	-	YES	8	-	YES	-	-
43	SV	136652	-	PROPESS	0	7.5	9.5	-	-	-	-	5	8	YES	6	YES	YES	-	-
44	GS	784545	-	PROPESS	0	24	27	-	-	-	-	5	8	YES	5	-	YES	-	-
45	SA	401220	-	PROPESS	0	14	16.4	-	-	-	-	4	7	YES	4	-	YES	-	-
46	AK	118006	-	PROPESS	0	14	17	-	-	-	-	3	8	YES	4	-	YES	-	-
47	M	766955	-	PROPESS	0	16	18	-	-	-	-	4	7	YES	5	YES	YES	-	-
48	SA	721366	-	PROPESS	0	17	22	-	-	-	-	5	7	YES	5	YES	YES	-	-
49	TG	775466	-	PROPESS	0	15	17.3	-	-	-	-	5	8	YES	3	-	YES	-	-
50	RK	655240	-	PROPESS	0	9	12	-	-	-	-	5	7	YES	5	-	YES	-	-

S NO.	INITIALS	MRD	ADVERSE EVENTS UTERINE HYPERSTIMULATION	FETAL DISTRESS	MSL	FD PLUS MSL	PPH	Uterine rupture	Retained Placenta	PATIENT SATISFACTION	NEONATAL OUTCOMES LIVE BIRTH	WEIGHT	SEX	APGAR SCORE AT 1 MINUTE	APGAR SCORE AT 5 MINUTES	indication of admission	ADMISSION TO NICU	NST AT ADMISSION REACTIVE
1	CK	688175	NO	-	-	-	-	-	NO	6	YES	2300	MALE	8	9	-	NO	YES
2	N	596194	NO	-	YES	-	-	-	NO	8	YES	2800	FEMALE	8	9	-	NO	YES
3	JK	271945	NO	-	-	-	-	-	NO	7	YES	2840	FEMALE	8	9	-	NO	YES
4	BK	90309	NO	-	-	-	-	-	NO	7	YES	3200	MALE	8	9	-	NO	YES
5	SM	586698	NO	-	-	YES	-	-	NO	9	YES	2580	FEMALE	8	9	-	NO	YES
6	MJ	661480	NO	-	-	-	YES	-	NO	8	YES	3440	MALE	8	9	-	NO	YES
7	T	660987	NO	-	-	-	-	-	NO	9	YES	3140	FEMALE	8	9	-	NO	YES
8	N	6718	NO	-	-	-	-	-	NO	7	YES	2910	MALE	8	9	-	NO	YES
9	SD	646993	NO	-	-	-	-	-	NO	9	YES	3040	MALE	8	9	-	NO	YES
10	R	509603	NO	-	-	-	YES	-	NO	8	YES	3600	FEMALE	8	9	-	NO	YES
11	MS	521656	NO	-	-	-	-	-	NO	9	YES	2480	FEMALE	7	8	-	NO	YES
12	KK	308591	NO	-	-	-	-	-	NO	7	YES	3240	MALE	8	9	-	NO	YES
13	P	535086	NO	-	-	-	-	-	NO	7	YES	2940	FEMALE	8	9	-	NO	YES
14	P	722181	NO	-	-	-	-	-	NO	9	YES	3520	FEMALE	8	9	-	NO	YES
15	I	7690	NO	-	-	-	-	-	NO	6	YES	2300	MALE	8	9	-	NO	YES
16	MK	723915	NO	-	-	-	-	-	NO	9	YES	3020	FEMALE	8	9	-	NO	YES
17	M	8080	NO	-	-	-	-	-	NO	7	YES	2000	MALE	8	9	-	NO	YES
18	SP	156646	NO	-	-	-	-	-	NO	8	YES	2900	MALE	8	9	-	NO	YES
19	K	585237	NO	-	-	-	-	-	NO	10	YES	2560	MALE	8	9	-	NO	YES
20	M	725499	NO	-	YES	-	-	-	NO	9	YES	3260	MALE	8	9	-	NO	YES
21	A	555898	NO	-	-	-	-	-	NO	8	YES	3740	MALE	8	9	-	NO	YES
22	H	731199	NO	-	YES	-	-	-	NO	9	YES	3200	MALE	8	9	-	NO	YES
23	MA	696539	NO	YES	-	-	-	-	NO	6	YES	3765	MALE	5	8	perinatal asphyxia	YES	YES
24	P	731310	NO	-	-	-	-	-	NO	6	YES	2400	MALE	8	9	-	NO	YES
25	AS	630723	NO	-	-	-	-	-	NO	7	YES	2880	FEMALE	8	9	-	NO	YES
26	PD	336477	NO	-	-	-	-	-	NO	8	YES	3020	FEMALE	8	9	-	NO	YES
27	MJ	735635	NO	-	-	-	-	-	NO	9	YES	2580	FEMALE	8	9	-	NO	YES
28	JK	62521	NO	-	-	-	-	-	NO	6	YES	3680	FEMALE	8	9	-	NO	YES
29	SJ	739144	NO	-	-	-	-	-	NO	7	YES	2800	MALE	8	9	-	NO	YES
30	KK	741792	NO	-	-	-	-	-	NO	9	YES	2900	FEMALE	8	9	-	NO	YES
31	MS	602816	NO	-	-	-	-	-	NO	7	YES	2800	FEMALE	8	9	-	NO	YES
32	SK	623773	NO	-	-	-	YES	-	YES	7	YES	2600	FEMALE	8	9	-	NO	YES
33	RK	550184	NO	-	-	-	-	-	NO	9	YES	3080	MALE	8	9	-	NO	YES
34	K	514702	NO	-	-	-	-	-	NO	9	YES	3140	FEMALE	8	9	-	NO	YES
35	P	775635	NO	-	-	-	-	-	NO	6	YES	3340	MALE	8	9	-	NO	YES
36	HK	618083	NO	-	-	-	-	-	NO	7	YES	3560	MALE	8	9	-	NO	YES
37	JB	490641	NO	-	-	YES	-	-	NO	8	YES	2560	MALE	8	9	-	NO	YES
38	SM	778412	NO	-	-	-	-	-	NO	6	YES	2880	FEMALE	8	9	-	NO	YES
39	N	742009	NO	-	-	-	-	-	NO	7	YES	2660	FEMALE	8	9	-	NO	YES
40	N	778247	NO	-	-	-	YES	-	NO	9	YES	3460	MALE	8	9	-	NO	YES
41	NG	63172	NO	-	-	-	-	-	NO	9	YES	2880	MALE	8	9	-	NO	YES
42	R	440090	NO	-	-	-	-	-	NO	9	YES	3300	MALE	8	9	-	NO	YES
43	SV	136652	NO	-	-	-	-	-	NO	6	YES	3420	FEMALE	8	9	-	NO	YES
44	GS	784545	NO	-	-	-	-	-	NO	8	YES	3100	FEMALE	8	9	-	NO	YES
45	SA	401220	NO	-	-	-	-	-	NO	9	YES	2620	MALE	8	9	-	NO	YES
46	AK	118006	NO	-	-	-	-	-	YES	9	YES	3360	MALE	8	9	-	NO	YES
47	M	766955	NO	-	-	-	-	-	NO	7	YES	2520	MALE	7	9	transient tachynea	YES	YES
48	SA	721366	NO	-	-	-	-	-	NO	8	YES	2820	MALE	8	9	-	NO	YES
49	TG	775466	NO	-	-	-	-	-	NO	9	YES	2120	MALE	8	9	meconium aspiration	YES	YES
50	RK	655240	NO	-	-	-	-	-	NO	7	YES	3320	FEMALE	8	9	-	NO	YES

S NO.	INITIALS	MRD	AGE	SOCIO-ECONOMIC STATUS	BOOKED	UNBOOKED/ BOOKED OUTSIDE	PERIOD OF GESTATION	PERIOD OF GESTATION GROUP	PRIMIGRAVIDA	MULTIGRAVIDA	SINGLETON PREGNANCY	INDICATION FOR INDUCTION OF LABOR_POSTDATISM	PPROM>24 HRS	PREECLAMPSIA	INTRAHEPATIC CHOLESTASIS OF PREGNANCY	GESTATIONAL DIABETES	FETAL GROWTH RESTRICTION	DECREASED FETAL MOMENTS
51	MK	741485	37	LM	YES	-	38 PLUS 1	2	YES	-	YES	-	-	-	-	YES	-	-
52	MA	661462	32	M	-	YES	39 PLUS 5	3	YES	-	YES	YES	-	-	-	-	-	-
53	AS	761672	30	U	-	YES	38 PLUS 5	2	-	YES	YES	-	YES	-	-	-	-	-
54	K	1550197	28	LM	YES	-	38 PLUS 1	2	-	YES	YES	-	-	-	-	YES	-	-
55	RK	7926	31	LM	YES	-	39	3	YES	-	YES	-	-	-	-	-	-	YES
56	MK	777197	25	M	-	YES	37 WEEKS	1	YES	-	YES	-	-	-	-	-	-	-
57	S	274789	30	U	-	YES	37 PLUS 5	1	-	YES	YES	-	-	-	YES	-	-	-
58	P	704514	29	U	YES	-	39 PLUS 4	3	-	YES	YES	-	-	-	-	-	-	YES
59	RB	800410	26	LM	YES	-	38 PLUS 6	2	YES	-	YES	-	YES	-	-	-	-	-
60	MK	9066	29	M	YES	-	37 PLUS 5	1	YES	-	YES	-	-	-	YES	-	-	-
61	AK	666855	25	U	-	YES	37 PLUS 6	1	YES	-	YES	-	-	-	-	-	-	-
62	J	120080	29	U	YES	-	40 PLUS 1	4	-	YES	YES	YES	-	-	-	-	-	-
63	AK	805499	32	LM	-	YES	37	1	YES	-	YES	-	YES	-	-	-	-	-
64	G	662319	26	LM	YES	-	38 PLUS 5	2	-	YES	YES	-	-	-	-	YES	-	-
65	SK	20669	31	M	-	YES	39 PLUS 3	3	-	YES	YES	-	-	-	-	-	-	YES
66	RK	811752	26	U	-	YES	39 PLUS 5	3	YES	-	YES	-	YES	-	-	-	-	-
67	S	811439	30	LM	YES	-	38 PLUS3	2	YES	-	YES	-	-	YES	-	-	-	-
68	P	80747	29	M	YES	-	37 WEEKS	1	YES	-	YES	-	-	-	YES	-	-	-
69	M	811907	28	U	-	YES	38 PLUS 6	2	YES	-	YES	-	-	-	-	-	-	-
70	SG	825404	25	LM	YES	-	37 PLUS 4	1	YES	-	YES	-	-	YES	-	-	-	-
71	HK	261541	24	U	YES	-	39	3	YES	-	YES	-	-	-	-	-	-	YES
72	S	682177	27	U	-	YES	37 PLUS 3	1	YES	-	YES	-	YES	-	-	-	-	-
73	R	821852	23	M	-	YES	40 PLUS 1	4	YES	-	YES	YES	-	-	-	-	-	-
74	DG	826348	28	M	YES	-	39 PLUS 1	3	YES	-	YES	-	-	-	-	-	-	YES
75	PS	8291	32	LM	YES	-	39 PLUS 4	3	YES	-	YES	-	-	-	-	-	-	YES
76	JK	582549	29	U	YES	-	37	1	YES	-	YES	-	-	-	-	-	YES	-
77	MV	517826	29	M	YES	-	37 PLUS 5	1	YES	-	YES	-	-	-	YES	-	-	-
78	AS	833300	28	M	YES	-	40	4	YES	-	YES	YES	-	-	-	-	-	-
79	PK	787023	26	LM	-	YES	37	1	YES	-	YES	-	-	YES	-	-	-	-
80	JK	247269	25	M	YES	-	38 PLUS 6	2	YES	-	YES	-	-	-	-	YES	-	-
81	BK	728609	32	M	YES	-	38 PLUS 5	2	-	YES	YES	-	YES	-	-	-	-	-
82	MD	838479	29	U	YES	-	39 PLUS 4	3	YES	-	YES	-	-	-	-	-	-	YES
83	RK	839472	35	LM	YES	-	37 PLUS 3	1	YES	-	YES	-	-	YES	-	-	-	-
84	S	820040	29	U	YES	-	40 PLUS 1	4	YES	-	YES	YES	-	-	-	-	-	-
85	AK	447911	30	U	YES	-	38 PLUS 3	2	YES	-	YES	-	-	-	-	-	-	-
86	GK	854413	25	U	-	YES	37 PLUS 2	1	YES	-	YES	-	-	-	YES	-	-	-
87	MS	840267	31	LM	YES	-	38	2	-	YES	YES	-	-	-	YES	-	-	-
88	AK	19118	33	LM	YES	-	38 PLUS 2	2	YES	-	YES	-	-	YES	-	-	-	-
89	M	71667	32	M	YES	-	38	2	YES	-	YES	-	-	-	-	-	-	-
90	SA	852419	28	M	-	YES	37 PLUS 6	1	YES	-	YES	-	-	YES	-	-	-	-
91	I	850132	24	M	-	YES	37	1	-	YES	YES	-	YES	-	-	-	-	-
92	HK	720344	33	LM	YES	-	40	4	YES	-	YES	YES	-	-	-	-	-	-
93	H	837705	32	U	YES	-	37	1	-	YES	YES	-	-	-	-	-	-	-
94	AJ	174596	28	U	YES	-	38 PLUS 3	2	-	YES	YES	-	-	-	-	YES	-	-
95	VG	288926	25	LM	YES	-	38 PLUS 2	2	-	YES	YES	-	-	-	YES	-	-	-
96	IS	749814	34	U	YES	-	39	3	-	YES	YES	-	-	-	-	-	-	YES
97	RS	651403	29	M	YES	-	38	2	YES	-	YES	-	-	YES	-	-	-	-
98	SG	636543	25	M	YES	-	40 PLUS 6	4	YES	-	YES	YES	-	-	-	-	-	-
99	H	791064	26	LM	YES	-	37 PLUS 1	1	YES	-	YES	-	-	-	-	-	-	-
100	MK	8339	29	U	YES	-	40	4	YES	-	YES	-	-	-	YES	-	-	-

S NO.	INITIALS	MRD	OTHERS	DRUG USED	GROUP	TIME INTERVAL BETWEEN INSTILLATION OF DRUG AND ONSET OF GOOD CONTRACTIONS	TIME OF DELIVERY	CERVIPRIME GEL MBS AT START OF INDUCTION	FIRST DOSE	SECOND DOSE	THIRD DOSE	PESSARY MBS AT START OF INDUCTION	AFTER 24 HRS	WAS INDUCTION SUCCESSFUL	NUMBER OF PV EXAMINATIONS	NEED OF OXYTOCIN	MODE OF DELIVERY VAGINAL DELIVERY	VD WITH FORECEPS	CESAREAN SECTION
51	MK	741485	-	PROPESS	0	12	17	-	-	-	-	4	7	YES	4	-	YES	-	-
52	MA	661462	-	PROPESS	0	-	24	-	-	-	-	3	4	NO	3	-	-	-	YES
53	AS	761672	-	CERVIPRIME	1	8	10	3	3	4	NA/VD	-	-	YES	5	-	YES	-	-
54	K	1550197	-	CERVIPRIME	1	4	6	4	4	NA/VD	-	-	-	YES	6	-	YES	-	-
55	RK	7926	-	CERVIPRIME	1	6	8	4	4	6	-	-	-	YES	9	-	YES	-	-
56	MK	777197	YES	CERVIPRIME	1	12	16	4	4	5	6	-	-	YES	11	YES	YES	-	-
57	S	274789	-	CERVIPRIME	1	9	11	4	4	5	NA/VD	-	-	YES	8	-	YES	-	-
58	P	704514	-	CERVIPRIME	1	12	14	5	5	6	-	-	-	YES	6	YES	YES	-	-
59	RB	800410	-	PROPESS	0	22	27	-	-	-	-	4	6	YES	13	-	-	-	YES
60	MK	9066	-	CERVIPRIME	1	18	24	4	4	5	6	-	-	YES	9	YES	YES	-	-
61	AK	666855	YES	PROPESS	0	8	10	-	-	-	-	4	7	YES	9	-	YES	-	-
62	J	120080	-	CERVIPRIME	1	12	14	5	5	6	-	-	-	YES	8	YES	YES	-	-
63	AK	805499	-	CERVIPRIME	1	5	8	5	5	NA/VD	-	-	-	YES	5	-	YES	-	-
64	G	662319	-	CERVIPRIME	1	-	8	5	5	NA/CS	-	-	-	NO	4	-	-	-	YES
65	SK	20669	-	CERVIPRIME	1	8	11	5	5	6	-	-	-	YES	7	-	YES	-	-
66	RK	811752	-	CERVIPRIME	1	24	29	4	4	4	5	-	-	NO	14	-	-	-	YES
67	S	811439	-	PROPESS	0	5	7	-	-	-	-	5	7	YES	9	-	-	-	YES
68	P	80747	-	PROPESS	0	12	18	-	-	-	-	3	6	YES	11	-	-	-	YES
69	M	811907	YES	PROPESS	0	12	19	-	-	-	-	4	7	YES	6	YES	-	-	YES
70	SG	825404	-	PROPESS	0	-	28	-	-	-	-	4	5	NO	3	-	-	-	YES
71	HK	261541	-	PROPESS	0	14	20	-	-	-	-	4	7	YES	7	YES	YES	-	-
72	S	682177	-	PROPESS	0	11	15	-	-	-	-	3	7	YES	12	YES	-	YES	-
73	R	821852	-	CERVIPRIME	1	-	11	3	3	3	4	-	-	NO	12	-	-	-	YES
74	DG	826348	-	CERVIPRIME	1	-	28	4	4	4	5	-	-	NO	13	-	-	-	YES
75	PS	8291	-	CERVIPRIME	1	-	27	4	4	4	5	-	-	NO	13	-	-	-	YES
76	JK	582549	-	CERVIPRIME	1	-	12	3	3	NA/CS	-	-	-	NO	7	-	-	-	YES
77	MV	517826	-	CERVIPRIME	1	9	12	3	3	NA/CS	-	-	-	NO	7	-	-	-	YES
78	AS	833300	-	PROPESS	0	-	8	-	-	-	-	3	NA/CS	NO	7	-	-	-	YES
79	PK	787023	-	PROPESS	0	-	27	-	-	-	-	3	4	NO	2	-	-	-	YES
80	JK	247269	-	PROPESS	0	-	29	-	-	-	-	3	4	NO	2	-	-	-	YES
81	BK	728609	-	PROPESS	0	16	21	-	-	-	-	4	7	YES	7	-	YES	-	-
82	MD	838479	-	PROPESS	0	-	30	-	-	-	-	3	4	NO	3	-	-	-	YES
83	RK	839472	-	PROPESS	0	6	12	-	-	-	-	4	5	NO	2	-	-	-	YES
84	S	820040	-	PROPESS	0	14	20	-	-	-	-	3	6	YES	9	-	-	-	YES
85	AK	447911	YES	CERVIPRIME	1	21	25	4	4	6	-	-	-	YES	11	-	-	-	YES
86	GK	854413	-	PROPESS	0	12	19	-	-	-	-	3	6	YES	8	-	-	-	YES
87	MS	840267	-	CERVIPRIME	1	-	9	3	3	NA/CS	-	-	-	NO	3	-	-	-	YES
88	AK	19118	-	PROPESS	0	8	28	-	-	-	-	3	5	NO	3	-	-	-	YES
89	M	71667	YES	CERVIPRIME	1	4	9	4	4	NA/VD	-	-	-	YES	5	-	YES	-	-
90	SA	852419	-	PROPESS	0	8	18	-	-	-	-	4	6	YES	5	-	-	-	YES
91	I	850132	-	CERVIPRIME	1	7	11	4	4	NA/VD	-	-	-	YES	6	-	YES	-	-
92	HK	720344	-	PROPESS	0	-	30	-	-	-	-	4	5	NO	3	-	-	-	YES
93	H	837705	YES	PROPESS	0	8	13	-	-	-	-	4	7	YES	8	YES	YES	-	-
94	AJ	174596	-	PROPESS	0	7	11	-	-	-	-	5	7	YES	5	YES	YES	-	-
95	VG	288926	-	CERVIPRIME	1	7	10	4	4	NA/VD	-	-	-	YES	7	YES	YES	-	-
96	IS	749814	-	CERVIPRIME	1	8	18	4	4	4	NA/CS	-	-	NO	9	-	-	-	YES
97	RS	651403	-	PROPESS	0	13	22.2	-	-	-	-	3	6	YES	6	-	-	-	YES
98	SG	636543	-	PROPESS	0	22	26	-	-	-	-	4	8	YES	4	YES	YES	-	-
99	H	791064	-	PROPESS	0	21	24	-	-	-	-	4	6	YES	10	YES	YES	-	-
100	MK	8339	-	CERVIPRIME	1	22	29	3	3	3	4	-	-	NO	13	YES	-	-	YES

S NO.	INITIALS	MRD	ADVERSE EVENTS UTERINE HYPERSTIMULATION	FETAL DISTRESS	MSL	FD PLUS MSL	PPH	Uterine rupture	Retained Placenta	PATIENT SATISFACTION	NEONATAL OUTCOMES LIVE BIRTH	WEIGHT	SEX	APGAR SCORE AT 1 MINUTE	APGAR SCORE AT 5 MINUTES	indication of admission	ADMISSION TO NICU	NST AT ADMISSION REACTIVE
51	MK	741485	NO	-	-	-	-	-	NO	6	YES	2340	MALE	7	9	-	NO	YES
52	MA	661462	NO	-	YES	-	-	-	NO	8	YES	3510	MALE	6	9	perinatal asphyxia	YES	YES
53	AS	761672	NO	-	-	-	-	-	NO	6	YES	2840	MALE	8	9	-	NO	YES
54	K	1550197	NO	-	-	-	-	-	NO	6	YES	3100	MALE	8	9	-	NO	YES
55	RK	7926	NO	-	-	-	-	-	NO	7	YES	2900	MALE	8	9	-	NO	YES
56	MK	777197	NO	-	-	-	-	-	NO	8	YES	2300	FEMALE	8	9	-	NO	YES
57	S	274789	NO	-	-	-	-	-	NO	7	YES	3100	MALE	7	8	others	YES	YES
58	P	704514	NO	-	-	-	-	-	NO	7	YES	3180	FEMALE	8	9	-	NO	YES
59	RB	800410	NO	-	YES	-	-	-	NO	8	YES	3340	FEMALE	6	8	-	NO	YES
60	MK	9066	NO	-	-	-	-	-	NO	7	YES	3200	MALE	8	9	-	NO	YES
61	AK	666855	NO	-	-	-	-	-	NO	6	YES	2600	MALE	8	9	-	NO	YES
62	J	120080	NO	-	-	-	-	-	NO	9	YES	3840	MALE	8	9	-	NO	YES
63	AK	805499	NO	-	-	-	-	-	NO	8	YES	2040	MALE	7	8	perinatal asphyxia	YES	YES
64	G	662319	NO	-	YES	-	-	-	NO	8	YES	2840	MALE	8	9	-	NO	YES
65	SK	20669	NO	-	-	-	-	-	NO	6	YES	2900	MALE	8	9	-	NO	YES
66	RK	811752	NO	-	-	-	YES	-	NO	8	YES	3840	MALE	8	9	-	NO	YES
67	S	811439	NO	-	-	-	YES	-	NO	9	YES	3360	MALE	6	9	meconium aspiration	YES	YES
68	P	80747	NO	-	-	YES	-	-	NO	9	YES	3420	MALE	8	9	-	NO	YES
69	M	811907	NO	-	-	-	-	-	NO	7	YES	3640	MALE	8	9	-	NO	YES
70	SG	825404	NO	-	-	-	-	-	NO	9	YES	2700	MALE	8	9	-	NO	YES
71	HK	261541	NO	-	-	-	-	-	NO	9	YES	3500	MALE	8	9	-	NO	YES
72	S	682177	NO	-	-	-	-	-	NO	8	YES	3060	MALE	7	9	others	YES	YES
73	R	821852	NO	YES	-	-	-	-	NO	7	YES	3760	FEMALE	8	9	-	NO	YES
74	DG	826348	NO	-	-	-	-	-	NO	7	YES	2930	MALE	8	9	-	NO	YES
75	PS	8291	NO	-	-	-	-	-	NO	6	YES	3000	MALE	8	9	-	NO	YES
76	JK	582549	NO	-	-	-	-	-	NO	9	YES	3600	GIRL	8	9	-	NO	YES
77	MV	517826	NO	YES	-	-	-	-	NO	7	YES	2960	MALLE	8	9	-	NO	YES
78	AS	833300	NO	-	YES	-	-	-	NO	9	YES	2380	MALE	8	9	transient tachynea	YES	YES
79	PK	787023	NO	-	-	-	YES	-	NO	9	YES	2660	FEMALE	8	9	-	NO	YES
80	JK	247269	NO	-	-	-	YES	-	NO	8	YES	3400	MALE	8	9	-	NO	YES
81	BK	728609	NO	-	-	-	-	-	NO	7	YES	3280	FEMALE	8	9	-	NO	YES
82	MD	838479	NO	-	-	-	YES	-	NO	6	YES	3760	FEMALE	8	9	-	NO	YES
83	RK	839472	NO	YES	-	-	-	-	NO	8	YES	2460	FEMALE	8	9	-	NO	YES
84	S	820040	NO	YES	-	-	-	-	NO	8	YES	3360	FEMALE	8	9	-	NO	YES
85	AK	447911	NO	-	-	-	YES	-	NO	7	YES	3580	MALE	8	9	-	NO	YES
86	GK	854413	NO	YES	-	-	-	-	NO	8	YES	2280	MALE	7	8	meconium aspiration	YES	YES
87	MS	840267	NO	YES	-	-	-	-	NO	7	YES	2720	MALE	8	9	-	NO	YES
88	AK	19118	NO	-	-	-	YES	-	NO	8	YES	3800	FEMALE	8	9	-	NO	YES
89	M	71667	NO	-	-	-	-	-	NO	8	YES	2860	MALE	8	9	-	NO	YES
90	SA	852419	NO	-	-	YES	-	-	NO	9	YES	2285	GIRL	8	9	-	NO	YES
91	I	850132	NO	-	-	-	-	-	NO	7	YES	2500	FEMALE	8	9	-	NO	YES
92	HK	720344	NO	-	-	-	-	-	NO	9	YES	3400	MALE	8	9	-	NO	YES
93	H	837705	NO	-	-	-	-	-	NO	8	YES	2860	MALE	7	8	perinatal asphyxia	YES	YES
94	AJ	174596	NO	-	-	-	-	-	NO	7	YES	2500	FEMALE	8	9	-	NO	YES
95	VG	288926	NO	-	-	-	-	-	NO	7	YES	2560	MALE	8	9	-	NO	YES
96	IS	749814	NO	YES	-	-	-	-	NO	9	YES	3270	FEMALE	8	9	-	NO	YES
97	RS	651403	NO	-	YES	-	-	-	NO	9	YES	3600	MALE	8	9	-	NO	YES
98	SG	636543	NO	-	-	-	-	-	NO	9	YES	3060	MALE	8	9	-	NO	YES
99	H	791064	NO	-	-	-	-	-	NO	9	YES	2200	MALE	8	9	-	NO	YES
100	MK	8339	NO	-	-	-	YES	-	NO	7	YES	2820	FEMALE	8	9	-	NO	YES

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The Principal,
DMC, Ludhiana.

Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 29.05.2019 has approved the plan of thesis of **Mehtab Kaur**, a student of your college for **MD Obstetrics & Gynaecology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis

To compare the effect of inducing agents dinoprostone sustained release vaginal pessary and intracervical gel on labour and its fetomaternal outcome

Supervisor
Dr. Ashima Taneja
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The student has to submit the four copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

SPSingh

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

1. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*
2. *The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.*

TO COMPARE THE EFFECT OF INDUCING AGENTS DINOPROSTONE SUSTAINED RELEASE VAGINAL PESSARY AND INTRACERVICAL GEL ON LABOUR AND ITS FETOMATERNAL OUTCOME

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

DOCTOR OF MEDICINE

IN OBSTETRICS/GYNAECOLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

NOVEMBER 2018

DR MEHTAB KAUR

DEPARTMENT OF OBSTETRICS/GYNAECOLOGY
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ABSTRACT OF PLAN OF THESIS

Title	TO COMPARE THE EFFECT OF INDUCING AGENTS DINOPROSTONE SUSTAINED RELEASE VAGINAL PESSARY AND INTRACERVICAL GEL ON LABOUR AND ITS FETOMATERNAL OUTCOME
For the degree of	MD Obstetrics and Gynaecology
Name of the candidate	Dr. Mehtab Kaur
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Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Induction of labour is an artificial initiation of uterine contractions before the onset of spontaneous labour that leads to progressive dilatation and effacement of cervix to achieve a vaginal delivery. Prostaglandin E2 is the preferred method of induction of labour. Two PGE2 preparations are commercially available: a gel available in a 2.5-mL syringe containing 0.5 mg of Dinoprostone and a vaginal insert containing 10 mg of Dinoprostone, The vaginal insert releases prostaglandins at a slower rate (0.3 mg/h) than the gel.

Aim: Aim of study This prospective randomized comparative study was done to compare the effect of inducing agents dinoprostone sustained release pessary with intracervical gel on labour..and its fetomaternal outcome.

Materials and Methods: A prospective simple random study is to be done on pregnant women >37 weeks of gestation admitted in Department of Obstetrics and Gynecology over a period of one year. Patients will randomly be offered dinoprosteone sustainesd release vaginal pessary or intracervical gel, The main outcome measures will betime interval between instillation of drug to development of good contractions, the mode of delivery, and the fetal outcome. The data would be statistically analyzed

Clinical significance: The most commonly prostaglandin preparation used is intracervical instant release gel, The disadvantages associated with its use are related to the invasive nature of administration, the frequency of dose repetition and the lack of a retrieval system if hyperstimulation occurs. Slow release vaginal preparations of PGE2 is being used in various countries for long and has an advantage of sustained physiological release of prostaglandin, resulting in slow and progressive cervical effacement, and it has retrieval system which allows immediate removal if hyperstimulation occurs, it can be kept for 24 hours that removes the need for repeated pelvic examinations..

Keywords: prostaglandin E2, dinoprostone, intracervical gel and vaginal pessary.

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CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **TO COMPARE THE EFFECT OF INDUCING AGENTS DINOPROSTONE SUSTAINED RELEASE VAGINAL PESSARY AND INTRACERVICAL GEL ON LABOUR AND ITS FETOMATERNAL OUTCOME** that exist in the Department of Obstetrics and Gynaecology, Dayanand Medical College and Hospital and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate herself under our supervision and guidance.

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5	TITLE OF THE TOPIC	TO COMPARE THE EFFECT OF INDUCING AGENTS DINOPROSTONE SUSTAINED RELEASE VAGINAL PESSARY AND INTRACERVICAL GEL ON LABOUR AND ITS FETOMATERNAL OUTCOME

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Induction of labour is an artificial initiation of uterine contractions before the onset of spontaneous labour that leads to progressive dilatation and effacement of cervix to achieve a vaginal delivery.

Labour induction should only be used in high risk pregnancies to protect the wellbeing of the fetus and the mother, and when the benefits of early birth outweigh the risks of continued pregnancy.[1]

The incidence of labour induction has continued to rise over the past several decades.[2] In developed countries, the number of infants delivered at term following induction of labor can be as high as one in four deliveries.[3-5] The World Health Organization (WHO) Global Survey on Maternal and Perinatal Health, conducted in 24 countries which included nearly 3,00,000 observations, showed that 9.6% of them were delivered by labor induction. The survey found that African countries have lower rates of induction of labour compared with Asian and Latin American.[6]

It is well established that the success of induction of labour is dependent upon the state of the cervix, and that with an unfavourable cervix, cervical ripening prior to induction is recommended.

There are various methods for induction of labour. When the cervix is in a favourable condition, labour can be induced by physical approaches to stimulate contractions of the uterus, including artificial rupture (amniotomy), sweeping or stripping of the membranes and the use of intrauterine catheters. Pharmacological approaches to induction of labour include the use of oxytocin and prostaglandins (PGE1 and PGE2). The most commonly used agent for

inducing labour is oxytocin, administered intravenously, which rapidly stimulates strong uterine contractions. However, it has no direct effect on the condition of the cervix [7] and the current studies seems to indicate that oxytocin is not as effective as the other pharmacological agents such as prostaglandins (PGE1, PGE2) for induction of labour.

PGE1 and PGE2 are forms of synthetic prostaglandins.

Misoprostol, a synthetic PGE1 analogue, can be administered intravaginally, orally, or sublingually and is used for both cervical ripening and induction of labour. It currently is available in a 100-mcg (unscored) or a 200- mcg tablet, and can be broken to provide 25-mcg or 50-mcg doses.

Two PGE2 preparations are commercially available: a gel available in a 2.5-mL syringe containing 0.5 mg of Dinoprostone and a vaginal insert containing 10 mg of Dinoprostone. Both are approved by the FDA for cervical ripening in women at or near term. The vaginal insert releases prostaglandins at a slower rate (0.3 mg/h) than the gel. Slow release dinoprostone (PGE2) vaginal pessary, has been licensed for use in India, for induction of labour (IOL), since June 2016.

There are various other dinoprostone preparations available, which has been used since the 1972's for induction of labour, which differ in their effectiveness and side effects.[8] The most commonly used is intracervical instant release gel, for which the evidence suggests that in females with unfavorable cervix, intracervical PGE2 is more effective than placebo, as an inducing agent, but it is less effective than vaginal PGE2, in achieving vaginal birth within 24 hours. The disadvantages associated with its use is related to the invasive nature of administration, and the frequency of dose repetition.[9]

Slow release vaginal preparations of PGE2 is being used in various countries for long and has an advantage of sustained physiological release of prostaglandin, resulting in slow and progressive cervical effacement, and it has retrieval system which allows immediate removal if hyperstimulation occurs. Also the application is easier and less invasive, with fewer dose requirement to achieve ripening of cervix and IOL [6]Dinoprostone vaginal delivery system is a controlled release hydrophilic matrix containing 10 mg. of dinoprostone, which provides a gradual release of the drug, releasing 03mg/hr in a controlled manner over 24 hours after single administration. The knitted polyester retrieval system allows easy removal if hyperstimulation occurs.[7] Furthermore, the sustained and controlled delivery of a low dose of dinoprostone avoids the administration of doses in excess amounts required to bring about cervical ripening and so eliminates the risk of 'dose dumping', which has been associated with an increased likelihood of adverse effects.

The risks are further reduced by the fact that the low dose of dinoprostone released from the pessary is rapidly cleared from the tissues. The presence of a retrieval system also means that the pessary can be rapidly and easily removed, immediately eliminating the source of dinoprostone.

In this study, we will carry out a comparative study to assess the clinical efficacy of dinoprostone sustained release vaginal pessary and intra cervical gel for induction of pregnant women of gestational age >37 weeks admitted for induction in the antenatal ward of Dayanand Medical College and Hospital, Ludhiana.

To our knowledge, this is the first study for publication in Punjab, comparing the commonly used PGE2 intra cervical gel to the recently available slow release vaginal pessary.

6.2 REVIEW OF LITERATURE

Over recent decades, more and more pregnant women around the world have undergone induction of labour (artificially initiated labour) to deliver their babies. In developed countries, up to 25% of all deliveries at term now involve induction of labour. In developing countries, the rates are generally lower, but in some settings they can be as high as those observed in developed countries.

The goal of induction of labor is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor. Generally, induction of labour has merit as a therapeutic option when the benefits of expeditious delivery outweigh the risks of continuing the pregnancy. The benefits of labor induction must be weighed against the potential maternal and fetal risks associated with this procedure.

The indications for induction of labour should take into account maternal and fetal conditions, gestational age, cervical status, and other factors.

Following are examples of maternal or fetal conditions that may be indications for induction of labour:

- Abruptio placentae
- Chorioamnionitis
- Fetal demise
- Gestational hypertension
- Preeclampsia, eclampsia
- Premature rupture of membranes
- Postterm pregnancy
- Maternal medical conditions (eg, diabetes mellitus,

renal disease, chronic pulmonary disease, chronic hypertension, antiphospholipid syndrome)

• Fetal compromise (eg, severe fetal growth restriction, isoimmunization, oligohydramnios)

Labor also may be induced for logistic reasons, for example, risk of rapid labor, distance from hospital, or psychosocial indications.

The contraindications to labour induction are the same as those for spontaneous labour and vaginal delivery. They include, but are not limited to the following situations:

• Vasa previa or complete placenta previa

• Transverse fetal lie

• Umbilical cord prolapse

• Previous classical cesarean delivery

• Active genital herpes infection

• Previous myomectomy entering the endometrial cavity

METHODS OF LABOUR INDUCTION

.MEMBRANE STRIPPING:-

Stripping or sweeping the amniotic membranes is commonly practiced to induce labor. Significant increases in phospholipase A2 activity and prostaglandin F2α (PGF2α) levels occur from membrane stripping. Stripping membranes increases the likelihood of spontaneous labor within 48 hours and reduces the incidence of induction with other methods.[10] Although membrane sweeping has been associated with increased risk of pre labor rupture of membranes, other published systematic reviews, including one with 1,525 women, have not corroborated this finding.[10] Women who undergo

membrane stripping may experience discomfort from the procedure as well as vaginal bleeding and irregular uterine contractions within the ensuing 24 hours

AMNIOTOMY

Artificial rupture of the membranes may be used as a method of labor induction, especially if the condition of the cervix is favorable. Used alone for inducing labor, amniotomy can be associated with unpredictable and sometimes long intervals before the onset of contractions. There is insufficient evidence on the efficacy and safety of amniotomy alone for labor induction . In a trial of amniotomy combined with early oxytocin infusion compared with amniotomy alone, the induction-to-delivery interval was shorter with the amniotomy-plus-oxytocin Method.[11]

CURRENT PHARMACOLOGICAL METHODS:

Oxytocin

Oxytocin is one of the most commonly used drugs. The physiology of oxytocin-stimulated labor is similar to that of spontaneous labor, although individual patients vary in sensitivity and response to oxytocin. Based on pharmacokinetic studies of synthetic oxytocin, uterine response ensues after 3–5 minutes of infusion, and a steady level of oxytocin in plasma is achieved by 40 minutes. The uterine response to oxytocin depends on the duration of the pregnancy; there is a gradual increase in response from 20 to 30 weeks of gestation, followed by a plateau from 34 weeks of gestation until term, when sensitivity increases. Any of the low- or high-dose oxytocin regimens outlined in Table below are appropriate for labor induction. Synthetic oxytocin generally is diluted 10 units in 1,000 mL of an isotonic solution for an oxytocin concentration of 10 mU/mL. Oxytocin should be administered by infusion

using a pump that allows precise control of the flow rate and permits accurate minute-to-minute control.

Regimen	Starting dose	Incremental increase (mu/ml)	Dosage interval(min)
LOW DOSE	0.5-2	1-2	15-40
HIGH DOSE	6	3-6 *	15-40

*The incremental increase is reduced to 3 mU/min in presence of hyperstimulatio and reduced to 1 mU/min with recurrent hyperstimulation.

Low-dose regimens and less frequent increases in dose are associated with decreased uterine tachysystole with associated FHR changes. High-dose regimens and more frequent dose increases are associated with shorter labor and less frequent cases of chorioamnionitis and cesarean delivery for dystocia, but increased rates of uterine tachysystole with associated FHR changes. Hypotension may occur following a rapid intravenous injection of oxytocin; therefore, it is imperative that a dilute oxytocin infusion be used even in the immediate puerperium.

Evidence related to the use of intravenous oxytocin for induction of labour at term was available from a Cochrane systematic review.[12] Compared with placebo or expectant management, the use of oxytocin alone was associated with fewer vaginal births not achieved within 24 hours of induction of labour

The use of intravenous oxytocin alone has also been compared with prostaglandins. Overall, the use of prostaglandins was associated with a Reduced risk of vaginal birth not achieved within 24 hours and fewer caesarean births. (WHO clinical guidelines for induction of labour)

PROSTAGLANDINS:

Misoprostol (PGE1): Misoprostol, a synthetic PGE1 analogue, can be administered intravaginally, orally, or sublingually and is used for both cervical ripening and induction of labor.

Several prospective randomized clinical trials and two meta-analyses have demonstrated that PGE1 (misoprostol) is an effective method for cervical ripening. Misoprostol administered intravaginally has been reported to be either superior to or as efficacious as dinoprostone gel.[13,14]

It is available in a 100mcg or 200mcg tablet. One quarter of an unscored 100-mcg tablet (i.e., approximately 25 mcg) of misoprostol should be considered as the initial dose for cervical ripening and labor induction. The frequency of administration should not be more than every 3–6 hours. In addition, oxytocin should not be administered less than 4 hours after the last misoprostol dose. Misoprostol in higher doses (50 mcg every 6 hours) may be appropriate in some situations, although higher doses are associated with an increased risk of complications, including uterine tachysystole with FHR decelerations.

The use of misoprostol in women with prior cesarean delivery or major uterine surgery has been associated with an increase in uterine rupture and, therefore, should be avoided in the third trimester.

Although misoprostol appears to be safe and effective in inducing labor in women with unfavorable cervices, further studies are needed to determine the optimal route, dosage, timing interval, and pharmacokinetics of misoprostol.

Its use, however according to current studies, is in case of nonviable pregnancies, in which vaginal misoprostol appears to be the most efficient method of labour induction, regardless of cervical Bishop score.

However, its has not been approved for use by DCGI (Drugs Controller General of India)

Prostaglandin E2 (PGE2)

It is the preferred method of induction of labour, unless there are specific clinical reasons for not using it.

Two PGE2 preparations are commercially available: a gel available in a 2.5-mL syringe containing 0.5 mg of dinoprostone and a vaginal insert containing 10 mg of dinoprostone. Both are approved by the FDA for cervical ripening in women at or near term. The vaginal insert releases prostaglandins at a slower rate (0.3 mg/h) than the gel.

Compared with placebo or oxytocin alone, vaginal prostaglandins used for cervical ripening increase the likelihood of delivery within 24 hours.

The recommended regimens are:

•One cycle of vaginal PGE2 tablets or gel: one dose, followed by a second dose after 6 hours if labour is not established (up to a maximum of three doses)

• One cycle of vaginal PGE2 controlled release pessary: one dose over 24 hours.

The intra cervical PGE2 gel (0.5 mg) has a 1% rate of uterine tachysystole with associated FHR changes while vaginal insert is associated with a 5% rate.[15] Uterine tachysystole typically begins within 1 hour after the gel or insert Removing the PGE2 vaginal insert usually will help to reverse the effect of uterine tachysystole. Irrigation of the cervix and vagina is not beneficial. Maternal side effects from the use of low-dose PGE2 (fever, vomiting, and diarrhea) are quite uncommon.

The manufacturers recommend that caution be exercised when using PGE2 in patients with glaucoma, severe hepatic or renal dysfunction, or asthma. However, PGE2 is a bronchodilator, and there are no reports of bronchoconstriction or significant blood pressure changes after the administration of the low-dose prostaglandin preparation.

The prostaglandin preparations should be administered where uterine activity and the FHR can be monitored continuously for a period of 30 minutes to 2 hours.

Swati et al determined the clinical efficacy dinoprostone sustained release vaginal pessary in India, comparing it with another preparation of dinoprostone which has been available and being used since years for IOL, i.e. instant released intracervical gel they found that the rate of caesarean section was more with the use of intracervical gel (37%) as compare to vaginal pessary (29%) and also the need of oxytocin was higher in intracervical gel group (72%) as compared to vaginal pessary group (51%).[16]

Kalkat et al demonstrated the clinical efficacy and cost-effectiveness of Dinoprostone Slow Release Pessary (Propess) with Gel (Prostin) for induction of labour (IOL) at term. They found that the number of vaginal examinations was significantly lower in the Propess group. Propess was found to be more cost effective compared with Prostin in view of single dose and less midwifery hours.[17]

Trigilia et al compared the 24-hour controlled-release vaginal dinoprostone pessary vs. gel for induction of labor at term in women with an unfavorable cervix. They found the rate of spontaneous vaginal delivery was significantly

higher in the pessary group (72%) than in the gel group (54%), paralleled by a lower rate of operative vaginal deliveries (3 vs. 15%).[18]

DEFINITION OF FAILED INDUCTION WITH PROPESS

The definition by NICE for failed induction with prostaglandin is "the failure to induce progressive labour after one cycle of treatment" in practice this means following the insertion of vaginal pessary for 24 hours.

6.3 AIMS AND OBJECTIVES OF THE STUDY

To compare the effect of inducing agents dinoprostone sustained release vaginal pessary with intracervical gel on labour and its fetomaternal outcome.

7.0 MATERIALS AND METHODS

7.1 SOURCE OF DATA

The study will be performed in the Department of Obstetrics and Gynaecology, Dayanand Medical College and Hospital, Ludhiana, which is a tertiary care hospital.

This will be a prospective study conducted over a period of 1 year, where patients will be enrolled starting from 1st January 2019 and followed for outcome till 31st December, 2019.

7.2 METHOD OF COLLECTION OF DATA

INCLUSION CRITERIA

Study population will consist of Booked/Un-Booked antenatal cases of gestation >37 weeks with singleton pregnancy, vertex presentation, t will include patients with Bishops score <6.

It will also include both primigravidae and multigravidae

EXCLUSION CRITERIA:-

1. Subjects with multiple pregnancy
2. Gestational age less than 37 weeks
3. Fetal presentation other than vertex
4. Having undergone previous uterine surgery (myomectomy, caesarean section)
5. Fetal distress
6. Patients with any contraindication to vaginal delivery or contraindication for labour induction by prostaglandin or oxytocin
7. Presence of uterine activity
8. Active vaginal bleeding

STUDY SAMPLE:-

The study will be performed on pregnant females selected for induction of labour > 37weeks period of gestation who are admitted in the antenatal ward from 1st January 2019 and followed till 31st December 2019.

METHOD:-

The study will be done on booked/unbooked pregnant women > 37 Weeks of gestation admitted in the antenatal ward of Dayanand Medical College and Hospital for induction of labour. After admission detailed history, systemic and obstetric examination, routine investigations and ultrasound will be done. Patients selected for induction and those who fulfilled the inclusion and exclusion criteria will be randomly divided into two groups (group A and B) according to a computer generated list. Informed consent for IOL taken.

Group A: Patients selected for intra vaginal insert, will receive a single dose of 10mg slow release dinoprostone vaginal insert placed transversely in posterior fornix of the vagina. The insert will be removed after 24 hours. It will be removed earlier if a non reassuring FHR pattern persisted, or if regular painful uterine contractions started.

Group B: Patients selected for intracervical gel, will receive the instant release gel preparation containing 0.5mg dinoprostone. A second or a maximum of three doses will be repeated every 6 hours if there is no adequate response.

Continuous electronic fetal heart monitoring will be done for 30 minutes after administration of prostaglandin, and after that 2 hourly CTG will be done till patient enters the active phase of labour

Induction failure will be considered when Bishops score is still less than 6 and

if regular uterine contractions do not start after 24 hours of prostaglandin use.

Stastical analysis will include T-test and Chi Square Test

The primary outcome measures studied were:

- Time interval between instillation of the drug to development of good uterine contractions
- time interval from induction of labour to delivery
- Mode of delivery : uncomplicated vaginal delivery, c section, foreceps
- Fetal outcome

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

All the above mentioned investigations are routinely performed as per the hospital guidelines. Hence will not pose any financial burden on the patient.

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Ethical Clearance attached herewith.

LIST OF REFERENCES

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(9) NICE Clinical Guideline number 70. Induction of Labour" (update of NICE inherited clinical guideline D) National Collaborating Centre for Women's and Children's Health (UK) London: RCOG Press; July, 2008

(10) Boulvain M, Stan C, Irion O. Membrane sweeping for induction of labour. Cochrane Database Syst Rev. 2005;1:CD000451.

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(15) Rayburn WF, Wapner RJ, Barss VA, Spitzberg E, Molina RD, Mandsager N, et al. An intravaginal controlled-release prostaglandin E2 pessary for cervical ripening and initiation of labor at term. Obstet Gynecol. 1992;79:374–9.

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(18) Triglia MT, Palamara F, Lojacono A, Prefumo F, Frusca T. A randomized controlled trial of 24-hour vaginal dinoprostone pessary compared to gel for induction of labor in term pregnancies with a Bishop score < or = 4. Acta Obstet Gynecol Scand. 2010;89:651-7.

PROFORMA

Sr No.

Name:- Age:- MRD number:-

Husband's name:- Admission number:-

Date of admission:-

Residential address:-

Booked/ Unbooked-

Past History

Family History

Socio-economic history

Nutritional History

Menstrual history:-

- LMP:-
- EDD:-

Obstetric history:-

- POG:-
- Obstetrical formula :
- Indication for induction of labor:-

Drug used	Time of Instillation of drugs	Time of onset of good contractions	Time of Delivery

Modified Bishops Score (MBS):

	Gel
MBS at Start of induction	
1st Dose	
2nd Dose	
3rd Dose	

Signature of Candidate **Signature of Supervisor**

	Pessary
MBS at Start of induction	
After 24 Hour	

Was Induction of labour successful **yes/no**

Need of Oxytocin Yes/ No

Time of start of Oxytocin	
Dosage	

Mode of delivery:- VD/Vd with forceps/C-section

ADVERSE EVENTS

1. Maternal complications:-

Uterine hyperstimulation- Yes/No

Retained placenta

PPH

Any other-

2. fetal complications:-

fetal distress

meconium stained liquor (MSL)

Fetal distress + MSL

Other:

Neonatal outcomes:-

Live Birth/Still Birth

Weight: Sex:

APGAR SCORE:- AT 1 MINS AT 5 MINS

Admission to NICU:- Yes/No

Indication of admission:-

INVESTIGATION:-

Hemogram:

NST at admission: Reactive/Non reactive:

Ultrasound:

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o.....

am willing to participate in the **study "TO COMPARE THE EFFECT OF INDUCING AGENTS DINOPROSTONE SUSTAINED RELEASE VAGINAL PESSARY AND INTRACERVICAL GEL ON LABOUR AND ITS FETOMATERNAL OUTCOME"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

.....
Signature of the Witness

Name:

.....
Signature of the patient

Signature of Candidate

Signature of Supervisor

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"TO COMPARE THE EFFECT OF INDUCING AGENTS DINOPROSTONE SUSTAINED RELEASE VAGINAL PESSARY AND INTRACERVICAL GEL ON LABOUR AND ITS FETOMATERNAL OUTCOME" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"TO COMPARE THE EFFECT OF INDUCING AGENTS DINOPROSTONE SUSTAINED RELEASE VAGINAL PESSARY AND INTRACERVICAL GEL ON LABOUR AND ITS FETOMATERNAL OUTCOME"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____

गवाह के हस्ताक्षर

नाम:

_____

रोगी के हस्ताक्षर/अंगूठे का निशान

नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर